EXHIBIT 11

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community connect

Shared Responsibility in Caring for the Person with Pain

The American Academy of Pain Management and Janssen Pharmaceuticals, Inc., are working together to conduct a number of **Community Connect** events throughout the United States in 2014.

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Articles/Expert Content & Case studies

Janssen Pharmaceuticals, Inc. has teamed up with leaders in pain management, psychology, and addiction, as well as other experts to develop *Prescribe Responsibly*.

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Pain Assessment Resources

Description of the location, duration, and other characteristics of pain is key to effective diagnosis and treatment. It's important to assess the impact of pain on the nature of the pain itself as well as the patient's quality of life.[56]

Healthcare professionals can use these scales to get a better understanding of their patients' pain, document changes, and set treatment goals for patients regardless of age or language barriers.

Brief Pain Inventory (BPI)[57]

- Self-administered patient questionnaire
- Questions address the impact of pain on psychosocial functioning
- Can be used to assess both pain intensity and degree of patient disability
- For patients with progressive conditions[58]

Roland Morris Disability Questionnaire[59]

- Designed specifically for the assessment of back pain and its attendant disabilities
- May be self-administered by the patient or used for discussion
- 24-point scale; higher score indicates greater disability
- Validated in both clinical and research settings[61]

Pain Assessment and Documentation Tool (PADT)[62]

- Two-sided chart note that can be easily included in the patient's medical record
- Assesses pain relief, side effects, and aspects of functioning as well as potential aberrant drug-related behavior[34]

Numeric Pain Intensity Scale and Pain Distress Scale[63]

- Patients are asked to rate their pain on a scale from 0 to 10, where 0 is no pain and 10 is extreme pain
- Scale allows for assessment of both pain intensity and degree of pain tolerance
- Can also be used to evaluate levels of disability and pain relief

Wong-Baker FACES® Pain Rating Scale[64,65]

- Uses drawings of various facial expressions (from smiling to crying) that indicate pain intensity

Pain Assessment Resources

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- May be used in patients aged 3 years and up
- Available in 30+ languages at www.WongBakerFACES.org

References Used in the Section:

56 Federation of State Medical Boards of the United States. Model guidelines for the use of controlled substances for the treatment of pain. Euless, TX: The Federation; 2004.

57 Brief Pain Inventory. Charles S. Cleeland, PhD. Pain Research Group. 1991.

58 National Pharmaceutical Council (NPC). Pain: current understanding of assessment, management, and treatments. NPC Web site. December 2001. http://www.npcnow.org/App_Themes/Public/pdf/Issues/pub_related_research/pub_quality_care/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf. Accessed June 5, 2011.

59 Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. *Spine*. 1983; 8;141-144.

61 Trout AT, Kallmes DF, Gray LA, et al. Evaluation of vertebroplasty with a validated outcome measure: the Roland-Morris Disability Questionnaire. *AJNR Am J Neuroradiol*. 2005;26(10):2652-2657.

62 Pain Assessment and Documentation Tool (PADT™). Janssen Pharmaceutical Products, L.P. 2003.

63 British Pain Society. Pain Rating Scale. http://www.britishpainsociety.org/pub_pain_scales.htm. Accessed June 5, 2011.

64 Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs*.1988;14(1):9-17.

65 Wong-Baker FACES® Foundation (2014). Wong-Baker FACES® Pain Rating Scale. Retrieved January 1, 2014 with permission from http://www.WongBakerFACES.org.

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STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #: _____

Brief Pain Inventory (Short Form)

Date: ____ / ____ / ____ Time: _____

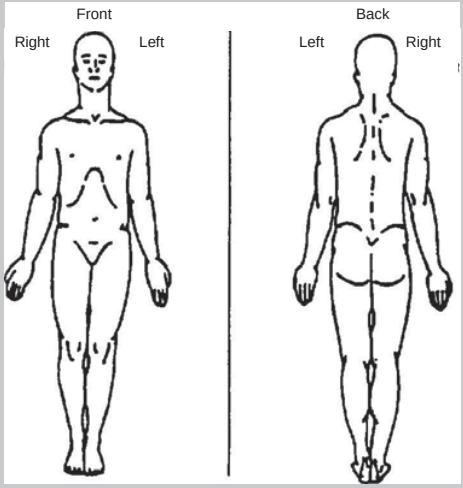
Name: _____ _____ _____

Last First Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

STUDY ID #:_____ DO NOT WRITE ABOVE THIS LINE HOSPITAL #:_____

Date:____/____/____ Time:_____

Name:_____ _____ _____

Last First Middle Initial

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.

13. My back is painful almost all the time.

14. I find it difficult to turn over in bed because of my back.

15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or stockings) because of the pain in my back.

17. I only walk short distances because of my back.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Note to users:

This questionnaire is taken from: Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine 1983; 8: 141-144

The score of the RDQ is the total number of items checked – i.e. from a minimum of 0 to a maximum of 24.

It is acceptable to add boxes to indicate where patients should tick each item.

The questionnaire may be adapted for use on-line or by telephone.

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Patient Name: _____ Record #: _____

Assessment Date: _____

Current Analgesic Regimen

Drug name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. **Ask the patient the questions below, except as noted.**

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.) _____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?
❑ Yes ❑ No

5. Query to clinician: Is the patient's pain relief clinically significant?
❑ Yes ❑ No ❑ Unsure

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	❑	❑	❑
2. Family relationships	❑	❑	❑
3. Social relationships	❑	❑	❑
4. Mood	❑	❑	❑
5. Sleep patterns	❑	❑	❑
6. Overall functioning	❑	❑	❑

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

(Continued on reverse side)

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever(s)? ❑ Yes ❑ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	❑	❑	❑	❑
b. Vomiting	❑	❑	❑	❑
c. Constipation	❑	❑	❑	❑
d. Itching	❑	❑	❑	❑
e. Mental cloudiness	❑	❑	❑	❑
f. Sweating	❑	❑	❑	❑
g. Fatigue	❑	❑	❑	❑
h. Drowsiness	❑	❑	❑	❑
i. Other _____	❑	❑	❑	❑
j. Other _____	❑	❑	❑	❑

2. Patient's overall severity of side effects?
❑ None ❑ Mild ❑ Moderate ❑ Severe

Potential Aberrant Drug-Related Behavior

This section must be completed by the physician.

*Please **check** any of the following items that you discovered during your interactions with the patient.* Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ❑ Purposeful over-sedation
- ❑ Negative mood change
- ❑ Appears intoxicated
- ❑ Increasingly unkempt or impaired
- ❑ Involvement in car or other accident
- ❑ Requests frequent early renewals
- ❑ Increased dose without authorization
- ❑ Reports lost or stolen prescriptions
- ❑ Attempts to obtain prescriptions from other doctors
- ❑ Changes route of administration
- ❑ Uses pain medication in response to situational stressor
- ❑ Insists on certain medications by name
- ❑ Contact with street drug culture
- ❑ Abusing alcohol or illicit drugs
- ❑ Hoarding (ie, stockpiling) of medication
- ❑ Arrested by police
- ❑ Victim of abuse

Other: _____

_____

_____

Assessment: (This section must be completed by the physician.)

Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? ❑ Yes ❑ No ❑ Unsure

Comments: _____

_____

Specific Analgesic Plan:

❑ Continue present regimen Comments: _____

❑ Adjust dose of present analgesic _____

❑ Switch analgesics _____

❑ Add/Adjust concomitant therapy _____

❑ Discontinue/taper off opioid therapy _____

Date: _____ Physician's signature: _____

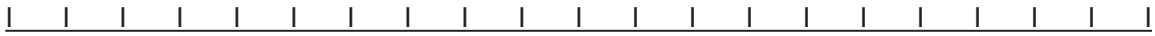
PAIN RATING SCALE

(English)

Title: ..... Date:.....
First Name:..... Patient number:.....
Surname:..... Clinic: .....

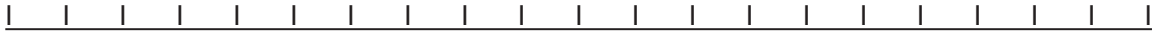
Please mark the scale below to show how intense your pain is.
A zero (0) means no pain, and ten (10) means extreme pain.

How **intense** is your pain **now**?



0 1 2 3 4 5 6 7 8 9 10
no pain extreme pain

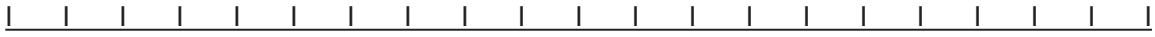
How **intense** was your pain **on average last week**?



0 1 2 3 4 5 6 7 8 9 10
no pain extreme pain

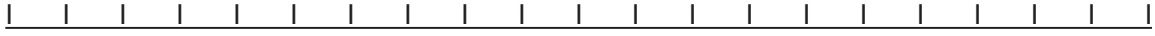
Now please use the same method to describe how **distressing** your pain is.

How **distressing** is your pain **now**?



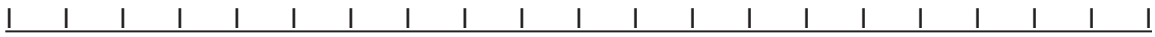
0 1 2 3 4 5 6 7 8 9 10
not at all distressing extremely distressing

How **distressing** was your pain **on average last week**?



0 1 2 3 4 5 6 7 8 9 10
not at all distressing extremely distressing

Now please use the same method to describe **how much your pain interferes** with your normal everyday activities.



0 1 2 3 4 5 6 7 8 9 10
does not interfere interferes completely

If you have had treatment for your pain, how much has this relieved (taken away) the pain?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
no relief complete relief

Wong-Baker FACES® Pain Rating Scale

0	2	4	6	8	10
No Hurt	Hurts Little Bit	Hurts Little More	Hurts Even More	Hurts Whole Lot	Hurts Worst

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Risk Assessment Resources

The initial evaluation of the patient in pain should include a risk assessment to identify those patients who may be at risk to misuse, abuse, or divert opioid analgesics. These resources can be used in conjunction with the patient's personal and family history to individualize the level of patient monitoring required in the treatment plan. After the initial assessment, the clinician should continue to monitor the patient carefully for treatment efficacy and possible evidence of opioid misuse.[66]

CAGE Questionnaire Adapted to Include Drugs (CAGE–AID)[67]

- Four-question screener to be administered by healthcare provider
- Assesses for potential drug and alcohol problems
- Evaluates risk based on the following 4 behaviors associated with substance abuse: feelings that one should "**C**ut down on substance use," becoming **A**nnoyed by criticism of substance use habits, feeling
- **G**uilty about one's use of substances, having an "**E**ye opener" in the morning to alleviate discomfort
- Affirmative answers to 2 out of 4 questions warrant further investigation[68]

Opioid Risk Tool (ORT)[69]

- Provider-administered survey consisting of 5 questions[66]
- Analyzes patient and family history to determine a risk category for the patient

Initiating Opioid Therapy

An **opioid agreement** should be considered to document and clarify treatment goals and expectations. It should help facilitate compliance and educate patients on responsible participation in their pain care. Opioid agreements are best used practice-wide to avoid bias. See table 2 for important points of an opioid agreemtent.

Sample Opioid Agreement

A sample agreement includes risk/benefit information and a list of potential opioid side effects.

- Washington State Department of Labor and Industries[70]

Clinical Opiate Withdrawal Scale[71]

- Widely used, healthcare professional–administered questionnaire[72]
- Asks provider to rate 11 signs and symptoms of opioid withdrawal as observed on a numerical scale

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References Used in the Section:

66 Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid therapy. http://www.agencymeddirectors.wa.gov/opioiddosing.asp. Accessed June 5, 2011.

67 Brown RL, Rounds LA. Conjoint screening questionnaires for alcohol and other drug abuse: criterion validity in a primary care practice. *Wis Med J*. 1995; 94(3):135-140.

68 National Institute on Drug Abuse. Diagnosis and treatment of drug abuse in family practice. http://archives.drugabuse.gov/diagnosis-treatment/diagnosis5.html. Accessed December 17, 2010.

69 Community Anti-Drug Coalitions of America. Opioid Risk Tool (ORT). http://www.preventrxabuse.org. Accessed June 5, 2011.

70 The Office of the Medical Director, Washington State Department of Labor and Industries. Opioid progress report. http://www.LNI.wa.gov/Forms/pdf/F245-359-000.pdf. Accessed June 5, 2011.

71 California Society of Addiction Medicine. Guideline for Physicians Working in California Opioid Treatment Programs. Table 6. Clinical Opiate Withdrawal Scale (COWS). www.csam-asam.org/files/CSAMOTPGuideline21Apr09.pdf. Accessed June 5, 2011.

72 Tompkins DA, Bigelow GE, Harrison JA, Johnson RE, Fudala PJ, Strain EC. Concurrent validation of the Clinical Opiate Withdrawal Scale (COWS) and single-item indices against the Clinical Institute Narcotic Assessment (CINA) Opioid Withdrawal Instrument. *Drug Alcohol Depend*. 2009;105(1-2):154-159.

The CAGE Questionnaire Adapted to Include Drugs (CAGE-AID)

1. **Have you felt you ought to cut down on your drinking or drug use?**
2. **Have people annoyed you by criticizing your drinking or drug use?**
3. **Have you felt bad or guilty about your drinking or drug use?**
4. **Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover (eye-opener)?**

Score: __ /4

2/4 or greater = positive CAGE, further evaluation is indicated

Source: **Reprinted with permission from the *Wisconsin Medical Journal.* Brown, R.L., and Rounds, L.A. Conjoint screening questionnaires for alcohol and drug abuse. *Wisconsin Medical Journal* 94:135-140, 1995.**

Opioid Risk Tool (ORT)

Questionnaire developed by Lynn R. Webster, MD to assess risk of opioid addiction.

MARK EACH BOX THAT APPLIES	FEMALE	MALE
FAMILY HISTORY OF SUBSTANCE ABUSE		
Alcohol	☐ 1	☐ 3
Illegal drugs	☐ 2	☐ 3
Rx drugs	☐ 4	☐ 4
PERSONAL HISTORY OF SUBSTANCE ABUSE		
Alcohol	☐ 3	☐ 3
Illegal drugs	☐ 4	☐ 4
Rx drugs	☐ 5	☐ 5
AGE BETWEEN 16–45 YEARS	☐ 1	☐ 1
HISTORY OF PREADOLESCENT SEXUAL ABUSE	☐ 3	☐ 0
PSYCHOLOGIC DISEASE		
ADD, OCD, bipolar, schizophrenia	☐ 2	☐ 2
Depression	☐ 1	☐ 1
SCORING TOTALS		

ADMINISTRATION

- On initial visit
- Prior to opioid therapy

SCORING (RISK)

0–3: low

4–7: moderate

≥8: high

Clinical Opiate Withdrawal Scale

Patient's Name:_____

Date and Time:_____/_____/_____

Resting Pulse Rate: _____beats/minute
Measured after patient is sitting or lying for one minute
0 pulse rate 80 or below
1 pulse rate 81-100
2 pulse rate 101-120
4 pulse rate greater than 120

Sweating: *Over past 1/2 hour not accounted for by room temperature or patient activity*
0 no report of chills or flushing
1 subjective report of chills or flushing
2 flushed or observable moistness on face
3 beads of sweat on brow or face
4 sweat streaming off face

Restlessness: *Observation during assessment*
0 able to sit still
1 reports difficulty sitting still, but is able to do so
3 frequent shifting or extraneous movements of legs/arms
5 Unable to sit still for more than a few seconds

Pupil size:
0 pupils pinned or normal size for room light
1 pupils possibly larger than normal for room light
2 pupils moderately dilated
5 pupils so dilated that only the rim of the iris is visible

Bone or Joint aches: *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored*
0 not present
1 mild diffuse discomfort
2 patient reports severe diffuse aching of joints/muscles
4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny nose or tearing: *Not accounted for by cold symptoms or allergies*
0 not present
1 nasal stuffiness or unusually moist eyes
2 nose running or tearing
4 nose constantly running or tears streaming down cheeks

GI Upset: *Over last 1/2 hour*
0 no GI symptoms
1 stomach cramps
2 nausea or loose stool
3 vomiting or diarrhea
5 Multiple episodes of diarrhea or vomiting

Tremor: *Observation of outstretched hands*
0 No tremor
1 tremor can be felt, but not observed
2 slight tremor observable
4 gross tremor or muscle twitching

Yawning: *Observation during assessment*
0 no yawning
1 yawning once or twice during assessment
2 yawning three or more times during assessment
4 yawning several times/minute

Anxiety or Irritability:
0 none
1 patient reports increasing irritability or anxiousness
2 patient obviously irritable or anxious
4 patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh skin:
0 skin is smooth
3 piloerection of skin can be felt or hairs standing up on arms
5 prominent piloerection

Total Score:_____
The total score is the sum of all 11 items
(5-12 = *mild* 13-24 = *moderate* 25-36 = *moderately* severe >36=*severe withdrawal)*

Initials of person completing assessment:_____

Reference: California Society of Addiction Medicine

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Hospital Pain Management Resources

Janssen Pharmaceuticals, Inc., is committed to improving pain management in hospitals and health care systems and supports their efforts to elevate quality and build and maintain high performing pain management services.

Awareness of pain management now plays an even more important role as it is one of the eight key topics that comprise the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The Patient Protection and Affordable Care Act of 2010 includes HCAHPS among measures that will be used to calculate value-based incentive payments which began with patient discharges in October 2012.

In partnership with the Join Commission Resources, Janssen Pharmaceuticals, Inc., is pleased to support a dedicated program that will allow hospitals and health care systems to assess, analyze, monitor, and improve their pain management service. **"Pain Management: A Systems Approach to Improving Quality and Safety,"** is a four-module resource designed to assist healthcare organizations in performing an objective assessment of existing strategies to manage pain and to use demonstrated performance improvement methods and tools to address gaps and improve performance in pain management from a systems approach. It includes the experiences of five healthcare organizations on their journey to improved pain processes.

Utilizing current knowledge about pain management processes can substantially benefit organizations by assessing current practice, identifying gaps, and implementing change. Doing so will improve business outcomes for value-based purchasing, enhance patient satisfaction and quality measures, and strengthen HCAHPS survey scores.

To learn more about our *Commitment to Improving Pain Management* in the Hospital click here

Full Module for Download

Pain Management: A Systems Approach to Improving Quality and Safety

The full modular set (Modules 1-4) is designed to help you perform comprehensive assessment, analysis, monitoring, and improvement of your pain management service at your health organization. The resource combines the four learning modules with case studies, tools, and self-study materials to form a valuable tool for leadership and staff

Pain Assessment Resources

- BPI
- PADT
- NRS
- Wong-Baker FACES® Pain Rating Scale

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Risk Assessment Resources

- CAGE -AID
- ORT
- Clinical Opiate Withdrawal Scale.

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Hospital Resources

- Make the Case
- Measure and Define
- Analyze and Improve
- Launch and Control
- Appendix/Toolkit

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AAPM – State Legislation & Regulation Tracking.

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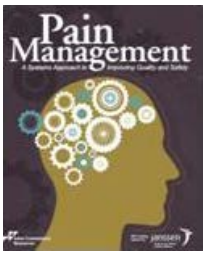

anywhere in the world.

Click here to order a free CD containing the full modular set. This link will take you to the Joint Commission Resources website and store.

Module Summaries

Module 1 Summary: Make the Case – *Assess and Improve Your Organization's Pain Management System*

Pain management is a complex health care challenge requiring system-wide assessment and organization-wide support, which means gaining committed support from senior leadership in your organization. This first module will help you:

- Make the case for assessing and improving your organization's pain management system
- Demonstrate the pain imperative
- Provide an overview of the project that includes the current state of pain management in your organization

Download Preview of "Module 1: Make the Case" as a PDF

Module 2 Summary: Define and Measure – *Assess How Pain is Managed in Your Organization*

This module will help you correctly identify gaps and shortcomings in the current process that is imperative to implementing improvement mechanisms. This includes:

- A system-wide assessment of your organization's pain management processes across multiple transitions of patient care
- Performing a pain system tracer
- Developing a high-level process map specific to how pain is managed in your organization
- Reading and understanding a case study specific to establishing priorities for pain management improvement

Download Preview of "Module 2: Define and Measure" as a PDF

Module 3 Summary: Analyze and Improve – *Determine Available and/or Needed Metrics for the Measurement of the Current State of Your Pain Management System*

A critical component of a successful pain management system is an organization's ability to build infrastructure that allows for safe, effective and efficient pain management systems and processes. This module focuses on:

- The provisions for a pain management infrastructure
- The promotion of the patient's continuous learning
- The transition of care for all stakeholders

Download Preview of "Module 3: Analyze and Improve" as a PDF

Module 4 Summary: Launch and Control – *The New Pain Management Process*

This module will help your team pilot test its new pain management process:

- Creating a deployment plan to set the new process into place smoothly
- Developing communication strategies that provide information vertically and

horizontally to all stakeholders in the health care organization, at ambulatory sites, and with community physicians and other clinicians.

This module helps reinforce the performance improvement framework to improve and sustain change.

Download Preview of "Module 4: Launch and Control" as a PDF

Appendix/Toolkit: Assess and Design New Pain Management Strategies

The tools and handouts in the appendix supplement Modules 1 - 4 . As you and your performance improvement (PI) team read through each module, you will find links to tools in discussions and analysis that will guide the team's assessment and design of the organization's new pain management strategies.

Download Preview of the "Appendix/Toolkit" as a PDF

In partnership with:

Joint Commission Resources

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Assess and Improve Your Organization's Pain Management System

Is your institution a top performer when it comes to minimizing patient pain?

Pain management is a complex health care challenge. In light of substantial industry changes under way regarding institutional reputation, value-based care models, and accountability, pain management has important implications for health care organization executives.

Today, real business needs with economic ramifications now require an assessment of the current pain services within individual health care systems.

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey

Value-based purchasing, patient satisfaction scores, and reports from the HCAHPS survey are all changing how services are evaluated and publicly reported.

The Centers for Medicare & Medicaid Services has created the HCAHPS survey. This standardized survey instrument and data collection methodology can be used for measuring a patient's perspective on his or her care. The survey has three core objectives:

1. Produce comparable data on patients' perspectives on care to enable objective and meaningful comparisons between health care organizations
2. Create incentives for health care organizations to improve quality of care
3. Enhance public accountability in health care through increased transparency

Pain management is one of the key 8 topics in the HCAHPS survey on patient perspectives

The Centers for Medicare & Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ) Team Up to Assess Patient Pain

As a purchaser, CMS will be seeking health care value for patients, which might include the active management and improvement of pain outcomes, as seen in the HCAHPS survey scores. In the summer of 2002, the CMS asked the AHRQ to develop an instrument to measure patient perceptions of care. The measurements were to be used to publicly report hospital performance (based on patient perceptions of quality of care), and this public reporting instrument would do the following:

- Provide consumers with information that might be helpful in choosing a health care organization.
- Complement rather than compete with quality improvement instruments already being used by health care organizations.
- Include 27 questions (stand-alone or embedded in an existing discharge survey) about recent hospital stays.
- Ask patients to rate the frequency of events during their care, using the scale "never," "sometimes," "usually," "always."
- Organize information under the following headings: Your Care from Nurses, Your Care from Doctors, The Health Care Environment, Your Experiences in the Health Care Organization, When You Left the Health Care Organization, Overall Rating of the Health Care Organization, and About You.

Survey questions are to be reported in the following areas:

- Communication with Doctors
- Communication with Nurses
- Responsiveness of Staff
- Pain Control
- Communication About Medicines
- Cleanliness of Health Care Organization Environment
- Quietness of Health Care Organization Environment
- Discharge Information
- Overall Health Care Organization Rating
- Likelihood to Recommend the Healthcare Organization

For more information, visit the AHRQ Web site, at https://www.cahps.ahrq.gov/content/products/HOSP/PROD_HOSP_Intro.asp.

Economic rationale for the improvement of pain management

The current state of pain management requires a systemwide assessment to identify gaps and improve the overall delivery of pain control services.

There are significant process improvement opportunities for health care organizations, and these, along with real market forces such as value-based purchasing, will play a role in the return on investment (ROI) potential for an individual organization.

Joint Commission Resources: Implementing a Successful Systemwide Approach

Effective pain management within our complex health care system does not happen as a matter of course; it requires knowledge of pain assessment and management, prevention strategies, documentation systems, and care coordination across individual care practitioners, diverse care teams, and patient care units.

Improving and establishing an effective pain management program requires a systemwide approach, championed by leaders who understand and support the value of minimizing a patients' experience of pain.

To better understand what is required to implement a successful systemwide approach, Joint Commission Resources consultants conducted site visits at several organizations (Duke University Hospital (NC), University of Miami

Hospital (FL), University of Wisconsin Hospital and Clinics (WI), St. Joseph's Baycare Health System (FL), and St. Peter's Health Care Services (NY)) that implemented successful improvement actions to minimize patient pain. The CD by Joint Commission Resources incorporates findings that result from critically analyzed events where health care systems most often fail in their management of pain.

Joint Commission Resources Lessons Learned

Joint Commission Resources consultants identified key lessons learned from the review of the site visits, including the following:

- The decentralized existence of providers of pain services contributes to confusion regarding who is accountable for managing the patient's pain
  - Clarity of roles and responsibilities is needed
- Patients frequently present with increased complexities in diagnosis, numerous comorbidities, and existing complex medication regimens. These complexities often are not known before a patient is admitted
  - Patients also enter via emergency services, often compromising the collection of complete and accurate history information. This dynamic creates patient safety issues and practitioner concerns
- Providers express fear related to over- or underadministration of pain medication, particularly opioids, and question their own competence in pain management
- It is not uncommon to find practitioners focusing more on documenting a patient's pain intensity on an objective scale than on being attentive to actually intervening to relieve the pain
- Physicians and staff have a wide variety of knowledge, skills, and interest in managing pain
- Clinical education updates are necessary for managing patients' pain-related needs
- Communication (oral and written) among health care providers, patients, and community practitioners leaves considerable room for improvement. New systems are needed to apply technology that quickly and reliably connects all care providers
- Many caregivers are frustrated that patients often use a drug before trying a simpler nonpharmacologic intervention, such as repositioning
- The issues of labor demands and time management continue to challenge organizations. Staff must often manually audit medical records to gather data. Information technology systems need to be optimized to quantify and qualify the data needs of patients with pain. Clinical resources and information technology support need to partner in solving this issue
- Organizations need to strive for continuous improvement of pain management
  - Use quality tools to analyze data

JCR consultants observed many creative pain management and safety practices during their site visits. Many sites use evidence-based practice interventions. On the right is a list of best practices.

Key Components for Building/Expanding a Pain Management Service

Joint Commission Resources consultants together with national pain advisors reviewed the literature, as well as the collected site visit data. Their review and discussion led to the identification of eight components appropriate for a systematic approach to pain treatment services. Here they are:

Module 1 will help you to:

- Assess and improve your organization's pain management system
- Understand the pain imperative and provide an overview of the project, including the need to determine the current state of pain management in an organization

Core objectives for this module include the following:

- Engage your organization in understanding the value and high priority of meeting current standards for pain control
- Crosswalk the tangible challenges of pain management to the specific needs of your organization
- Identify the potential for external review of a health care organization to assess the following:
- Gaps in the existing pain management program
- Opportunities to continuously improve organizational pain management efforts using a performance improvement approach
- Describe the eight components of an effective pain management program
- Use a case study to facilitate your organization's understanding of specific needs in the areas described in this module

Best Practices Gleaned from Site Visits

Evidence-based practice interventions used at site-visit organizations include the following:

- The use of color as a safety practice was impressive. For example, the operating room of one organization switches the patient's head cap to one of a different color to indicate completion of the time-out at the transition from preoperative care to the operating room.
- Unit-based nurse pain champions attended to pain-specific needs.
- Each site had acute pain services primarily serving inpatients with acute postoperative pain.
- All sites showed appreciation for and compliance with the pain standards.
- Each site recognized education and competencies as being important, but not all sites had the capacity to prepare and teach relevant pain content to their staff.
- A few sites had pharmacy involvement in bedside pain rounds. All these sites displayed respect and appreciation for the depth of pharmacy involvement.
- One site described its chronic pain clinic and used it as an extended resource beyond acute care.
- A variety of communication techniques were used to keep all staff updated on advances in pain management.
- Some of the education resources were designed to be available 24/7 in electronic form.
- All sites found measurement requirements challenging and were hopeful that some vendors would offer products or services to address their needs to extract data electronically from the medical record.

The Eight Critical Components

These eight critical components are necessary for building and/or expanding a systemic pain service:

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders

Joint Commission Resources

Janssen Pharmaceuticals, Inc.

May 2012

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Assess How Pain Is Managed in Your Organization

Is your institution a top performer when it comes to minimizing patient pain?

Assessing your organization's current pain management process is a crucial step, as performance improvement (PI) tools will positively impact the systems approach only if gaps and shortcomings in the current process are correctly identified.

Keys to Pain Management System Assessment

- Develop a pain management PI team
- Outline key roles for pain management PI systems
- Appoint appropriate individuals to those roles

Key Players for a Pain Management PI Team

Role	Description
Executive sponsor	A senior leader who sponsors the overall pain initiative, for example a Chief Nurse Executive (CNE), and who reports to the Chief Executive Officer (CEO) or Chief Operating Officer (COO).
Pain project champion	A middle- or senior-level leader who sponsors a specific pain project, ensuring that resources are available and that cross-functional issues are resolved.
Pain project manager	An individual who is responsible for implementing PI pain projects, communicating with the senior leader champion, setting agendas, facilitating the use of PI tools, and providing oversight for project phases.
Interdisciplinary pain team members	Professionals who bring relevant experience or expertise to the management of patients in pain and who work together to provide a pain management system that is safe, effective, and efficient.
Pain resource nurse	A designated nurse in each work area who functions as a peer resource for pain management issues.
Process owner	A professional who is responsible for the business process that is the target of a PI project. For instance, if the pain team implements a change in pain management in the emergency department (ED), the process owner may be the ED director who provides oversight to the change process and is responsible for sustaining the improvement when the project is over.

Use a systematic PI methodology to move your team from problem definition to planning and management

The PDCA/PDSA (plan, do, check/study, act) cycle, the Lean Sigma, or Six Sigma are some of the commonly used PI methods. Each of these methods applies a systematic process by using data collection plans, and applies solution-generation methods to target root causes, and leads to the implementation of postlaunch control or monitoring plans.

How do you identify and describe the current state of the issue or concern relative to pain management?

An organization's pain management PI team can use the following tools to define their current state:

- WOT analysis
- System tracer
- High-level process map
- Project charter

System tracers as a PI tool

A system tracer is a vital component of Joint Commission's on-site accreditation survey. As a PI tool, a system tracer helps an organization visualize and document current issues and concerns.

Sample Tracer Questions

Questions for the Pain Committee and Senior Leaders

- How do you obtain relevant, up-to-date information regarding pain management?
- How do you disseminate this information to other staff at all levels?
- What are the greatest pain-related risks facing your organization?
- What are you doing to diminish the risks and impact on outcomes of care?
- How do you monitor compliance with the requirements of pain standards?
- How do you intervene when you observe noncompliance?
- How do you collect and analyze data that may help reveal risky or problematic trends and patterns?
- What is your involvement on the committee?
- Why were you selected to be on this committee?
- What data are being studied?
- How are data communicated to you?
- Do you compare and benchmark your data and outcomes with others?
  - Describe this process.
  - How do you compare?
- What improvements have you implemented?
  - Have they been effective?
  - How do you know?
- How are staff performing regarding safe, effective, and efficient pain management?
  - Is improvement sustained, and is it sustainable?
  - How do you know?

Questions for the Clinicians Across the Continuum

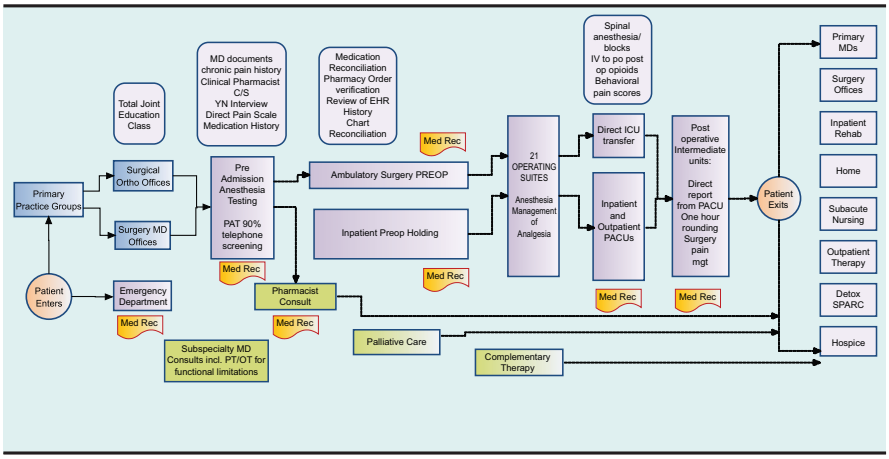
- Do you have a pain management protocol or process?
- How do you monitor for continuity of care?
- How do you monitor for compliance with protocols?
- How do you know whether patients and families are engaged in decisions about pain treatment?
- Do you intervene if you believe the relevant guidelines are not being complied with? How?
- How do you educate patients and families?
- How do you document this education?
- Do you have an electronic medical record (EMR), or do you rely on paper charts?
- How does your pain management information flow across your EMR or paper charts?
- What types of integrative or complementary and alternative medicine techniques do you use to manage pain?
- What are your resources and levels of support for patients and their families?
- What would you like to see change?

The Power and Value of a Process Flow Map

Creating a process map may clarify how work is actually performed. It helps in determining whether staff work together or in separate functional groups (sometimes referred to as "silos" or "swim lanes"). It also clarifies:

- The work requirements of different team members
- The sequence followed in the care process
- Whether the needs of the customers are being met

In most cases, a process map begins with the identification of a customer need and documents the flow of information and activities to achieve that need and satisfy the customer's expectations. Here's a process map example:



*The patient entry and exit is depicted as circles in pink, medication reconciliation is amber, patient flow with nursing is violet, preadmission and postdischarge stakeholders and pain assessments and treatments are light blue, and the pain resource consultations are in green.

The Functional Flow Map: A High-Level Process Map

One specific type of high-level process map is referred to as a functional flow map, or swim lanes diagram. A swim lanes diagram allows a team to see what each separate discipline or pain management resource is doing. Using this type of map is helpful when all involved are working within individual silos. The swim lanes diagram is an example of how a team can illustrate and describe the various functional requirements within the pain management system.

Pain Management Clinical Nurse Specialists	Pain consult service; Nursing practice and innovation; Pain care team; Pediatric and integrative therapies; Manage pain resource nurses; Pediatric resident rotation and training; Pharmacist collaboration/ consult
Acute Pain Service	Manage assigned patient populations; Regional blockade; Epidural cath protocols; 24/7 coverage; Residency and fellowship programs; IV Ketamine infusions
Inpatient Rehab	3 hr/day rehab; Pain mgt to enable therapies; Integrative medicine: Acupuncture, massage; non-steroidal assessment; Local/topical opioids TENS; Intrathecal therapy coverage; Sole/one MD coverage
Chronic Pain Clinic	Multidisciplinary clinic; Pharma pain mgt; Phyisical Tx, healthy psych; Surgery referral; Neruopathic pain mgt and peds coverage; No management of pain and addiction
Addiction Medicine Service	Consultation service; Diagnosis of addiction; Guide care and treatment; Small service/ wait times; No management of pain and addiction

This Module will help you to:

- Develop a team to assess your organization's current pain management process
- Address the first five components of the eight critical components of a successful pain management program

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders

Core objectives for this module include the following:

- Describe the first five key components of an effective pain management system
- Perform a systemwide assessment of your organization's pain management processes across multiple transitions of patient care
- Perform a pain system tracer
- Develop a high-level process map specific to how pain is managed in your organization
- Define potential PI opportunities, based on the current state analysis and write a team-based project charter
- Establish an interdisciplinary pain management PI team
- Read and understand a case study specific to establishing priorities for pain management improvement

Determine Available and/or Needed Metrics for the Measurement of the Current State of Your Pain Management System

Pain Management Infrastructure

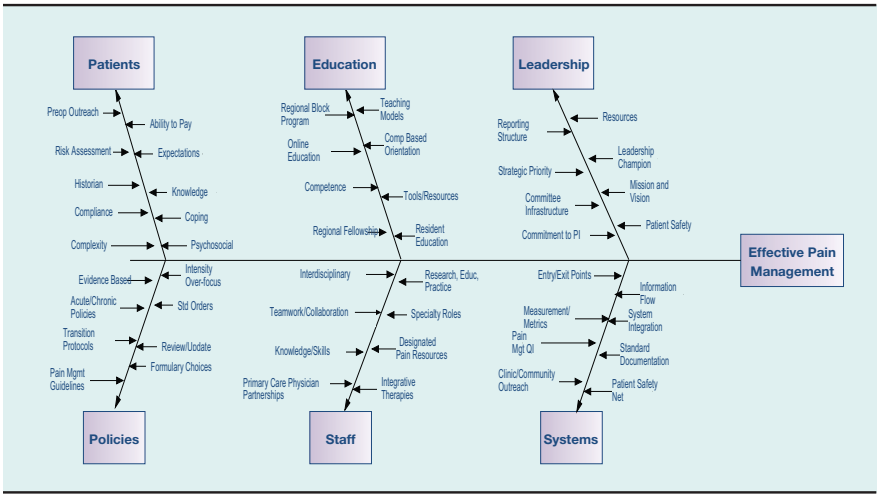
A critical component of a successful pain management system is an organization's ability to build infrastructure that allows for safe, effective, and efficient pain management systems and processes. The pain management PI team and its executive sponsor will provide and maintain resources to improve performance.

Gap Analysis

After a high-level process has been mapped, the PI team will scrutinize each process step to identify and discuss potential defects. A process tool that has traditionally been used to highlight potential causes is known as the cause-and-effect diagram.

- The cause-and-effect diagram is an excellent PI tool that enables teams to anticipate as many potential failures as possible
- When a PI team begins to generate solutions and redesign their current state process, they can be assured that the highlighted prioritized variables can be addressed, and potential failures can be eliminated

A Cause-and-Effect Diagram is shown here:



In addition, a team can also generate a list of gaps or deficiencies in practices, processes, and outcomes that may need to be addressed and measured prior to designing the ideal state for the new processes and pain system. This Gap analysis is illustrated in the table below:

Strategic Variable	Measurement	Current Standing	Deficiency	Action Plan
Interdisciplinary pain team	Present/absent	Does not exist	Lack of collaborative pain management practice	Create an interdisciplinary pain team
Pain assessment and reassessment documentation	% compliance, by unit	80%	20%	Initiate a PI project
Required educational resources	Compliance rates by discipline	MD 20%, Nursing 80%	80%, 20%	Restate requirements to practice and manage accountability
Access to specialty referral	15-minute turnaround time—phone call	Turnaround time averages 1.5 hours	1.25 hours	Initiate a PI project to determine root cause
Individual pain goal	Daily shift assessment present/absent	Noncompliance with individual pain goal policy	50%	Initiate PI project that includes stakeholders, patient, and family

Measurement and Metrics

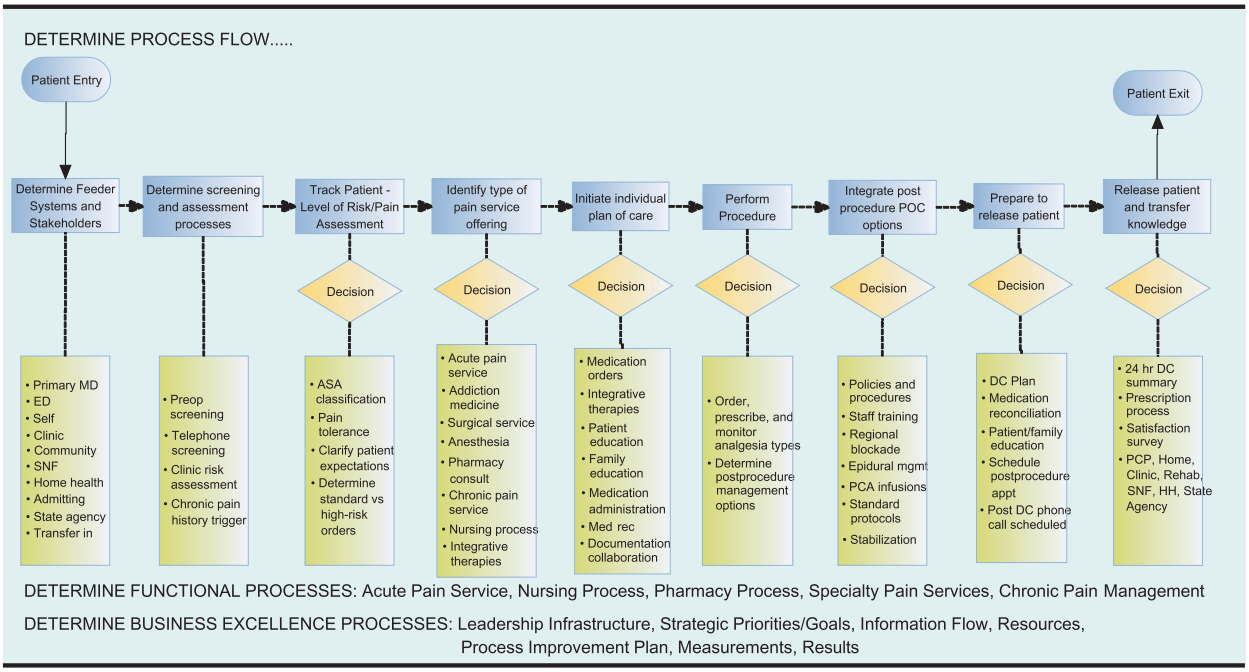
A PI team needs to consider how it will measure the overall impact of a project. To do so, the PI team needs:

- Baseline and current pain management system data so that improvements, both in pilot testing and posttest design, can be evaluated
- A full understanding of the current state
- Process and outcome metrics in a simple and direct format at the initiation of a project to shape the team's understanding of what the ideal state can look like

What Will Your Pain Management System Look Like: The Ideal State

A pain team needs to develop a future state vision and an ideal state process for safe, effective, and efficient pain management across transitions of care.

The pain team should also have a solid appreciation of what works in the current state and what does not. At this point, the team should have identified cause-and-effect variables, and there should be an understanding of potential gaps in the system. Based on the analysis of root cause variables, the team can brainstorm solutions that will permit a smooth transition from the current state to the future state, and the team can now prepare to pilot test the new process. The following diagram illustrates a team's ideal state:



Failure Mode and Effects Analysis (FMEA)

A pain team needs to develop a future state vision and an ideal state process for safe, effective, and efficient pain management across transitions of care. Many aspects of safe and effective pain care can be viewed both as the translation of best practices into daily clinical care and the avoidance of failures such as intervals of preventable severe pain or undesirable side effects. Therefore, a preemptive analysis of possible failure modes complements the construction of an ideal state. Based on a team's review of the ideal state model it has created, the team should use FMEA to double-check for failures before pilot testing the new design. The use of HEALTH care FMEA is an easy and efficient way to generate potential failures.
A team needs to review each process task or function and ask the following questions:

1. What process or subprocess is prone to be excessively repeated?
2. What process or subprocess is prone to occur in the wrong sequence?
3. What process or subprocess is prone to occur either too early or too late?

Health Care Failure Modes

Failure Type	Examples: Pain Management Failures
Omission failures	Not using age or language-specific pain assessment tools Failure to assess response to pain management treatment options
Excessive repetition	Repeating medication doses without using complementary therapy/alternatives
Wrong sequence	Misreading or misunderstanding physician orders
Early or late execution	Failure to manage pain therapies in a timely way
Incorrect identification/selection	Not checking for compatible medications or prescribing opioids, for instance, for a patient with pulmonary disease
Incorrect information	Incorrect route and/or setting for a PCA pump

This Module will help you to:

- Develop a team to assess your organization's current pain management process
- Address the last three components of the eight critical components of a successful pain management program

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders

Core objectives for this module include the following:

- Use your SWOT assessment and high-level process map of the current state to identify organizational gaps specific to the management of patients' pain
- Develop a cause-and-effect diagram that highlights variables that may impact the effectiveness of your organization's pain management system
- Complete a FMEA of key patient-centered variables that affect pain management
- Create a future vision and potential design for the ideal state of pain management in your institution
- Develop a measurement system to assess the impact of changes made from the current state of pain management in your organization toward the ideal state
- Generate solutions for effective management of pain across transitions of care
- Read and understand a case study specific to analyzing and improving pain management systems

The New Pain Management Process

Pilot Testing

- Have you implemented any new initiatives?
- What changes have occurred?
- Do you see the need to make adjustments?

After pilot testing your newly-designed (or redesigned) pain management program, the organization's pain management performance improvement (PI) team will be able to address these important questions.

The Deployment Plan

Effective launch and control includes the incorporation of a deployment plan, which identifies activities, who is responsible, and when relevant implementation will occur. A deployment plan provides clarity around the sequence of activities needed to initiate and maintain effective change.

What? Changes	How? Actions	Who? People	When? Start	When? Complete	Measure? Results
People (new pain resource nurse)					
Process					
Equipment (new patient-controlled analgesia [PCA] pumps)					
Materials					
Environment/location					
Replicate					

The deployment plan requires oversight. A monitoring plan requires a process owner to take responsibility and sustain the new process. A solid communications strategy is essential for sustainability of the new pain management process – use multiple communication approaches to reinforce understanding and support for your new pain management process:[1]

- People remember 10% of what they read
- People remember 20% of what they hear
- People remember 35% of what they see
- People remember 50% of what they read, hear, and see
- People remember 70% of what they say
- People remember 90% of what they do

Communication between providers and across practice settings aligns with the continuity of care needs and patient satisfaction, both of which can positively impact the market share of institutions.

Does your institution have the capacity to launch and control a new or redesigned pain service?

To answer this important question, an organization should have already assessed the current pain management process, built a pain management PI team, applied a systematic PI methodology to identify root causes, and developed a measurement system to evaluate changes from the current state to one that fills gaps and provides the vision for design of the new or ideal pain management service. These next five factors will provide insight as to how quickly and successfully improvement can be implemented.

A review of these questions can provide insights into an organization's capacity to launch and control.

- Can a trial test (pilot) be easily conducted?
- Is the change difficult to understand?
- Compared to current practice, what value-added change does the change offer?
- Is the change compatible with the organization's environment and culture?
- How easy is it for leaders and opinion makers to view the benefits of the change?

Site Visit Feedback

The five health care organizations in the national pain initiative reported on their progress, post-visit, no longer than four months following the initial consultant site visit. The post-visit questions and highlights of the responses are listed here:

1. **What priorities or system opportunities did the pain team identify in the gap analysis? Explain how your organization addressed them. (For example, if lack of education was perceived as a priority, you may have developed an orientation program.)**

- One site identified five priorities for improvement:
  - To ensure appropriate, safe, and timely pain management, the inventories and functioning of PCA devices, epidural infusion pumps, and oximeters were reviewed. Required equipment is now available and functional
  - Processes were established to improve patient safety. For example, order forms now use standardized drug concentrations; hard limits on highest and lowest infusion rates are programmed on all pumps used for pain control; the pharmacy does not process orders provided in any format other than on the standard pain relief order forms; and policies for pain are now cross-referenced across departments for consistency
  - Education programs are provided for orientation, nurse residency programs, the pain resource nurse program, and both physician and pharmacist education are regularly reviewed and revised, as needed
  - Evidence-based tools are used. For example, the organization is now using literature, surveys of community hospitals, standards of practice for PCA and epidurals, and the Critical Care Pain Observation Tool (CCPOT)
  - Documentation opportunities have arisen with new flow sheets and policies
- Another site identified four opportunities:
  - Providers at multiple pain management sites need to collaborate
  - Standards regarding handoffs and transitions of care are lacking and must be strengthened or developed and then implemented
  - Efforts must be made to address the wide variety of information technology systems that do not speak to each other
  - The process map needs to be finalized to convey the total system view

- Collectively, the sites indicated the following priorities:
  - Developing a process for clinicians to ask questions and/or relay concerns
  - Competency-based pain education is needed for all clinicians
- Sites also identified other needs as they redesigned their pain programs:
  - Identifying an executive sponsor
  - Restructuring reporting relationships for pain personnel
  - Realigning the pain program with the strategic goals and performance improvement framework for the entire system
  - Enhancing the electronic medical record
  - Reviewing chronic pain services available in the continuum of care
- A community hospital reported the following:
  - The need for education, toolkits, and resources for pain management
  - Unit-based/service-line pain resource nurses
  - Pain management orders for new admissions from the emergency department
  - Sanctioning of a pain management task force

2. **What have been the most significant challenges to implementing the improvements?**

- Lack of structure for discussion and resource sharing across services
- Struggle to define a metric for ROI and identify appropriate resources for the business model
- Competition with other organizational priorities
- Difficult procurement process for purchasing and problematic budget and capital planning cycle
- Scheduling training so that it does not compete with clinical care needs of patients
- Lack of time
- Selection of an interdisciplinary pain team
- Finding a dedicated interdisciplinary pain consulting service

3. **What were the strengths you identified in your organization's pain management system, and how have you expanded them or used them as a basis for moving forward? Some of the following existed already, and others were in the new design plan:**

- Unit-based pain champions, including pharmacists
- Physician champion volunteering during the redesign process
- Healing touch program
- Steady increase in referrals to the pain service
- Support for outpatient clinic pain interventions
- Financial support
- Full compliance with Joint Commission pain standards
- A learning center

- An interdisciplinary approach
- Patient identification of their own pain goals
- Integrated therapies such as TV, music, Wii, and massage
- Resources available to clinicians 24/7
- Evidenced-based practices and clinical guidelines
- Order sets and assessment flow sheets
- Six Sigma classes at one organization

4. **What additional needs does your organization have in order to continue its commitment to improving pain management?**

- An advisory panel of high-level leaders
- Filling of clinical vacancies
- A physician champion
- A model for the transition of care across the continuum
- Various methods of pain relief measures
- Ongoing education
- Identification of performance measures
- Continued leadership support
- Continued collaboration and motivation with national pain practices
- Creation of an annual plan
- Sanctioning of a pain management resource service
- Engagement of the community

5. **What three activities of Joint Commission Resources consultant site visit were most helpful?**

- The presence of outside consultants quickly organizing, collating, analyzing, and presenting concrete, specific site data; participation of high-level leaders; and new insights gained
- The use of the pain tracer survey method, which has improved communication between disciplines
- PowerPoint tools using specific site data in a process map, SWOT analysis, and a cause-and-effect diagram, which provided greater understanding of current state; sharing feedback on leading practices; appreciation for the business opportunities

6. **What could be different, in terms of support from Joint Commission Resources?**

- A more specific site visit agenda and schedule
- A full narrative summary in addition to the PowerPoint presentation
- Identification of data elements for measurement
- Periodic webinars and networking opportunities for pain clinicians
- Earlier contract review
- More time with the final presentation and recommendations
- A broadened tracer that includes medical patients

Feedback following the consultant visits revealed both similarities and differences between organizations. Use these questions to understand the findings and needs in your own organization.

Core objectives for this module include the following:

- Pilot test your new pain management process
- Create a deployment plan to set the new process into place smoothly
- Develop communication strategies that provide information vertically and horizontally to all stakeholders in your health care organization, at ambulatory sites, and with community physicians and other clinicians
- Plan celebrations to honor and showcase the team and its accomplishments
- Share lessons learned
- Reinforce the performance improvement framework to improve and sustain change

Reference

1. Arthur J.: *Lean Six Sigma Demystified.* New York: McGraw-Hill, 2007.

Joint Commission Resources

Janssen Pharmaceuticals, Inc.

May 2012

02UNB12004A

Assess and Design New Pain Management Strategies

Using the Tools

The tools and handouts in the appendix should be used in conjunction with the text of Modules 1-4. As you and your performance improvement (PI) team read through each module, you will find links to tools in discussions and analysis that will guide the team's assessment and design of the organization's new pain management strategies.

Tool Kit Components

- Pain Expert Biographies
- *Acute Post-Surgical Pain Management: A Critical Appraisal of Current Practice*, Rathmell et al.
  - The Pain Summit Survey
- Key Roles for Pain Management
- Form for Assigning Key Roles
- Sample Pain Team Agenda
- Defining Lean Waste and Potential Failure Modes (**See example**)
- Practical Tracer Example: The Laboratory Tracer (**See example**)
- Instructions for Developing a High Level Process Map and Swim Lane Diagram (**See example**)
- Project Charter: Pain Management
- University of Wisconsin Health Center Core Competency Worksheet
- University of Wisconsin Health Center Health Facts: What You Should Know About Pain Management (a tool for patients, their families and caretakers)

Defining Lean Waste and Potential Failure Modes

Lean methods, originating from the Toyota Production System (TPS), have been used to eliminate errors and waste in system processes. The DOWNTIME acronym is used to remember the different types of Lean waste — see below:

Defining Lean Waste and Potential Failure Modes

Within every process, there are opportunities to eliminate lean waste. Lean Thinking—or more simply Lean—began as Toyota's Production System Model and is a system of tools and principles used to create solutions to problems by increasing the value-added delivery to the customer by reducing waste. Easily recalled by the acronym **DOWNTIME**, waste exists in the following eight forms:

- **D**efects – failure modes, for example:
  - Omission of pain medication, omission of follow up assessment
  - Incorrect selection of medication, failure to provide
  - Discharge prescriptions
  - Incomplete discharge instructions
  - Failure to assess patient comprehension
  - Omission of device and medical equipment ordering
- **O**verproduction – overproduction of DC teaching sheets that are not individualized or become outdated
- **W**aiting – wait times for patients, staff and faculty
- **N**on value-added processing – rework and redundancies
- **T**ransportation – not enough wheel chairs creating discharge delays
- **I**nventory – over or under supplying medications or discharge materials
- **M**otion – having to run for things, stoop, stretch, pull or push inappropriately – having supplies/materials at the point of service will eliminate excess motion
- **E**mployee (underutilizing and/or not using staff-based knowledge) – lean kaizen events use the staff who do the actual "work" to be a part of the problem solving process (all shifts and weekends represented as needed).

After high level maps are created, the team can begin to visualize the various types of waste at each step within the process. The goal of every lean process is to eliminate waste and thereby eliminate any future errors in the process.

Tracer Example: The Laboratory Tracer

Laboratory tracers are unique because they do not focus solely on direct patient contact as tracers in other accreditation programs do. Instead, the laboratory tracer evaluates the performance of processes, with particular focus on integrating and coordinating distinct but related processes. The tracer also assesses the interrelationships among departments, programs, services, or units to identify strengths and weaknesses and potential concerns in the relevant processes. Here is a checklist and a mock tracer tracking worksheet:

Tips Checklist

Consider the following strategies when conducting a laboratory tracer:

- ***Focus on issues of particular concern for laboratories and process interfaces with clinical staff.*** Consider those issues of particular concern to a laboratory, such as patient identification, quality control, and communication of critical test results. You can use these specific topics to plan a specialized tracer using a closed medical record.
- ***Consider your laboratory's past testing activity as a starting point.*** It can be very informative to conduct a tracer of past testing activity, particularly if a pattern of near-miss reports or quality control problems with a particular test have been observed.
- ***Select the medical record of a patient who received multiple laboratory tests, including tests performed at point-of-care sites.*** This will help you look at multiple processes within your laboratory at one time. Follow the testing from the time of the order to the action taken, if indicated.
- ***Instead of one person conducting the tracer, consider walking through one as a group.*** Having an informal group discussion as you verbally "trace" through a closed medical record can help laboratory staff to better understand tracers. This is also a good opportunity to discuss possible "workarounds" or other potential problems that could result in a negative outcome.
- ***Don't forget to consider the beginning and end of a process, not just the outcome.*** For example, while tracking a specimen, make sure that you are following the work done by staff to both collect and then test that specimen. Observe work done with patients. Observe how patient identification is being performed. It is important to remember that tracers can be used to follow an entire process or system, and your goal should be to determine if there are any gaps or potential missteps.

Mock Tracer Tracking Worksheet: The Laboratory Tracer

Use this worksheet to record notes and areas of concern that you identify while conducting your organization's mock tracers. This information can be used to highlight a good practice or to determine issues that may require further follow-up. "Yes" or "no" indicates whether the staff member interviewed during the tracer answered the question correctly.

Tracer Team Member: _____ Tracer Patient or Medical Record: _____
Staff Interviewed: _____
Unit or Department Where Tracer Was Conducted: _____

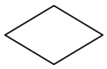
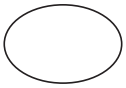
TRACER QUESTIONS	YES	NO	FOLLOW-UP NEEDED	COMMENTS OR NOTES
Describe your laboratory process to handle transfusion reactions.				
What training and orientation have been provided to laboratory staff to handle transfusion reactions?				
What data and analysis have you done on the incidence of transfusion reactions in your organization?				
What measures have you introduced, if any, to reduce the incidence of transfusion reactions?				
What initial assessment do you perform for new transfusion patients?				
What were the specimen collection requirements for the tests performed for this tracer patient? Where were they collected?				
What process did you follow for preparing blood units for this patient's transfusion in an outpatient setting?				
What instructions did you provide to this tracer patient?				
What is your laboratory's policy for ordering a stat procedure?				
How do you verify orders for laboratory testing? How do you determine who is authorized to give those orders?				
What is your quality control process? When is corrective action required?				
What is your quality control process for the basic metabolic panel?				

Acces this entire two-page worksheet at
http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.

Instructions for Developing a High Level Process Map and Swim Lane Diagram

Process mapping is a technique for making work visible. A process map shows who is doing what, with whom, when and for how long. It also shows decisions that are made, the sequence of events, and any wait times or delays inherent in the process. The Process Map is a horizontally aligned flow chart that maps the specific process from start to finish. The facilitator asks the group what the high level steps in the process are and those steps are placed on the flip chart. Once the initial draft of the process map is created, it will be important for the team to verify the map by "going and seeing" what actually happens (Walk the Walk). Invariably, what the team members "think" is happening in the process is not consistent with what they "see" on their walk. The team will then come together again to discuss their findings and redesign their initial process map.

There are a variety of graphical shapes that can be used in flow charting but the most common shapes used are the following:

Box 	Activities, tasks, steps in the process
Diamond 	Decisions
Circle 	Start and end steps
Arrow	To connect each of the activities, decisions or start and end points

Process maps are good for streamlining work activities and telling new people, as well as internal and external customers, "what we do around here." They also can help in the effort to reduce cycle time, avoid rework, eliminate some inspections or quality control steps, and prevent errors.

- Use the tools (like the examples above) provided in the appendix to define and measure, analyze and improve, and launch and control a new pain management program

ER/LA Opioid Analgesics REMS

The Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy

Lo ere.

IMPORTANT SAFETY LABEL CHANGES!

Revised Indication:

- For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Revised Warnings:

- ADDICTION, ABUSE and MISUSE
- LIFE-THREATENING RESPIRATORY DEPRESSION
- ACCIDENTAL INGESTION
- CYTOCHROME P450 3A4 INTERACTION

New Warning:

- NEONATAL OPIOID WITHDRAWAL SYNDROME

Please click on the U.S. Prescribing Information link for the complete label for each ER/LA opioid drug.

RISK EVALUAT

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- **Counsel Your Pa**
  ER/LA opioid ana
  these medicines.
- **Emphasize Patie**
  patients and their
  receive from their
- **Consider Using**
  tools to improve patient, household and community safety, as well as compliance with conditions of treatment, including Patient-Prescriber Agreement (PPA) and risk assessment instruments

Click here for a complete list of products covered under the ER/LA Opioid Analgesics REMS Program

For additional information about the ER/LA Opioid REMS Program, call 800-503-0784.

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Medication Guides
Healthcare Professional Frequently Asked Questions

Materials for Patients

Medication Guides
Patient Frequently Asked Questions

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Last Updated: October 24, 2014

ER/LA Opioid Analgesics REMS

The Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy

Looking for Accredited REMS CME/CE? Click Here.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

The FDA has required a REMS for extended-release and long-acting (ER/LA) opioid analgesics.

Under the conditions specified in this REMS, **prescribers of ER/LA opioid analgesics are strongly encouraged to do all of the following:**

- **Train (Educate Yourself)** - Complete a REMS-compliant education program offered by an accredited provider of continuing education (CE) for your discipline
- **Counsel Your Patients** - Discuss the safe use, serious risks, storage, and disposal of ER/LA opioid analgesics with patients and/or their caregivers every time you prescribe these medicines. Click here for the Patient Counseling Document (PCD)
- **Emphasize Patient and Caregiver Understanding of the Medication Guide** - Stress to patients and their caregivers the importance of reading the Medication Guide that they will receive from their pharmacist every time an ER/LA opioid is dispensed to them
- **Consider Using Other Tools** - In addition to the PCD, there are other publicly available tools to improve patient, household and community safety, as well as compliance with conditions of treatment, including Patient-Prescriber Agreement (PPA) and risk assessment instruments

Click here for a complete list of products covered under the ER/LA Opioid Analgesics REMS Program

For additional information about the ER/LA Opioid REMS Program, call 800-503-0784.

Accredited Continuing Education for Healthcare Professionals

REMS-Compliant CE for ER/LA Opioid Analgesics

Listing of Accredited CME/CE REMS-Compliant Activities Supported by RPC ***UPDATED***

Continuing Education Provider Information

Materials for Healthcare Professionals

Dear DEA-Registered Prescriber Letter

Patient Counseling Document

Medication Guides

Healthcare Professional Frequently Asked Questions

Materials for Patients

Medication Guides

Patient Frequently Asked Questions

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Policy & Advocacy

The Academy is the country's leader in pain management policy and advocacy.

The Academy is widely recognized as the nation's foremost voice in proposing and advocating for public policy that allows its members and other healthcare practitioners to provide optimal pain care.

Become a Member of the Academy

OUR APPROACH TO POLICY

The Academy's policy and advocacy team works with members of Congress and federal regulatory agencies to ensure that they recognize uncontrolled pain as a public health crisis and to design policies that offer effective practical solutions without negative unintended consequences.

STATE PAIN POLICY ADVOCACY NETWORK

No other organization advocates for optimal pain management policy in all 50 states. A collaboration among more than 100 organizations, the Academy's State Pain Policy Advocacy Network (SPPAN) program rallies advocates and gives them the tools they need to effectively influence policy.

PAIN DOES MATTER

Pain Matters examines pain management through the experiences of six individuals living with chronic pain. The Academy's Director of Policy and Advocacy, Bob Twillman, Ph.D., served as an expert consultant and commentator for this important documentary.

The Importance of Advocacy

Bob Twillman, PhD, discusses why advocacy is necessary and how the Academy approaches it.

Our Mission: Advocating for Balanced State and Federal Policy

It's critical that policymakers hear the voices of pain management advocates. The Academy carries the balanced policy message through its federal policy efforts and its State Pain Policy Advocacy Network (SPPAN).

Our Federal Policy Efforts

The Academy is the only pain management organization in the U.S. with a dedicated, in-house Policy and Advocacy Department, which is directed by Bob Twillman, PhD — one of the nation's most respected pain policy leaders. Dr. Twillman carries the Academy's positions on key issues to policy makers on Capitol Hill and elsewhere in the Washington DC area, as well as in state capitals throughout the country, educating them on the Academy's mission and the importance of good integrative pain care.

Our State Policy Initiative

The Academy's State Pain Policy Advocacy Network (SPPAN) project is led by its Director, Amy Goldstein, MSW. SPPAN coordinates advocacy efforts in all 50 states by members of more than 100 organizations concerned about pain management policy. Helping these disparate groups speak with one voice amplifies our message and ensures that our ability to steer policymakers toward good, balanced, pain management policy is unparalleled.

Take Action

We need the help of advocates like you. Take action and change the pain management world for the better.

FIND ELECTED OFFICIALS

Search for elected officials in your area.

ACCESS ADVOCACY RESOURCES

Read the latest news and information related to pain policy.

REVIEW LEGISLATION AND REGULATION

Access our database of legislation and regulation related to the pain management field.

"Membership keeps me informed and [gives me] access to new pain treatments."

LISA ZARETZKY, BSC, PHARM
MEMBER SINCE 2011

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Responsible Pain Management

On this site you will find case studies that can help you assess various clinical scenarios that you may encounter in your practice. You will also find articles written by experts on topics that address the use of opioids in pain management, what you should know before writing prescriptions for opioids, and much more.

Please watch the introductory video by Dr. Paul Chang, Vice President of Medical Affairs in Internal Medicine at Janssen Pharmaceutical Companies.

We hope the information you find here is useful in your practice and in your management of patients with pain.

Pain Assessment Resources

- BPI
- PADT
- NRS
- Wong-Baker FACES® Pain Rating Scale

read more

Risk Assessment Resources

- CAGE -AID
- ORT
- Clinical Opiate Withdrawal Scale.

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Hospital Resources

- Make the Case
- Measure and Define
- Analyze and Improve
- Launch and Control
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AAPM – State Legislation & Regulation Tracking.

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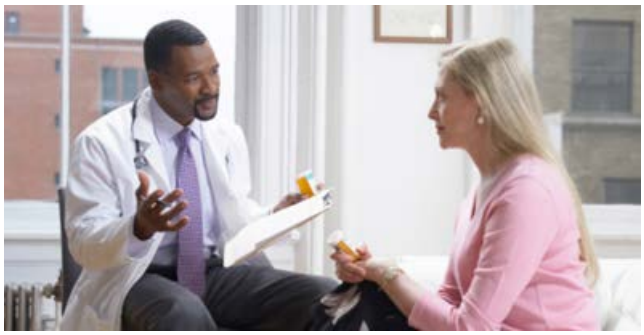
Mixed Pain States



by **Charles E. Argoff, MD**

Expert authors received compensation from Janssen Pharmaceuticals, Inc. for their contributions to PrescribeResponsibly.com

Chronic pain is a multifaceted disease often requiring multimodal treatment. The elucidation of both peripheral and central nervous system pain mechanisms, outlined in more detail below, has provided insights into the biochemical, molecular, and neuroanatomic correlates of chronic pain. Treatment selection should be guided by comprehensive assessment of the phenomenology and inferred pathophysiology of the pain syndrome (ei, mechanism-based treatment); patient goals, preferences, and expectations; behavioral, cognitive, and physical function; and level of risk for adverse events and observant behaviors.

The experience of either acute or chronic pain involves a complex process associated with the activation of multiple neuronal signaling pathways within the peripheral nervous system (PNS) and central nervous system (CNS).[75-77] Additionally, inhibitory and excitatory processes mediated through multiple descending pathways, including the opioid, monoaminergic and other pathways, may modulate pain transmission, resulting in either antinociceptive or pronociceptive effects.[78,79] The variety of mechanisms involved in pain signaling and modulation provides a number of potential targets for different pharmacological interventions.[80] Clinical observation suggests that single analgesic therapies are often insufficient to provide adequate pain relief, and are consistent with findings regarding the complexity of pain signaling and the recognition that mixed mechanisms of pain often underlie a patient's chronic pain complaints.[81,82] These observations have led not only to the recognition of the conceptual framework of "mixed pain" but also to the practice of utilizing analgesic agents (multidrug therapy) with different mechanisms of action in an attempt to maximize efficacy and tolerability.[81,82] This approach has become a recommended treatment strategy for different types of acute and chronic pain.[83-85]

Exploring Key Mechanisms of Pain Transmission and Its Modulation

Pain perception results from a series of neurophysiologic events occurring within the PNS and CNS.[75] Transduction is the process by which noxious stimuli are converted into electrical activity within the PNS and it begins with activation of specialized nerve endings known as peripheral nociceptors.[76,

Pain Assessment Resources

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[79] Painful stimuli cause the opening of various ion channels and flux of ions across cell membranes within the peripheral nociceptive afferent.[76, 85] Certain stimuli may result in depolarization and generation of action potentials that are then conducted via peripheral afferents to the dorsal horn of the spinal cord with the subsequent release of excitatory neurotransmitters (eg, glutamate), neuropeptides (eg, substance P), and neuromodulators (eg, brain-derived neurotrophic factor [BDNF]) from axon terminals into the synapse within the dorsal horn.[76, 79, 85] These neurotransmitters/modulators then bind to and activate receptors on the postsynaptic nerve terminal, including N-methyl-D-aspartic acid (NMDA), α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA), G protein–coupled receptors and tyrosine kinase receptors.[79,85] Should these presynaptic action potentials occur at a sufficient frequency and duration, the activity in the postsynaptic terminal will increase, and another action potential will be propagated. Those impulses generated in the dorsal horn travel through ascending pathways (eg, the spinothalamic tract) to the brain, where the signals are processed and pain is perceived.[75, 79]

Peripheral nociceptive afferent activity can be augmented if tissue damage has occurred due to the release of pro-inflammatory factors, such as bradykinin, prostaglandin E_2, nerve growth factor, and tumor necrosis factor-alpha (TNF-α).[76, 79, 86] These mediators, after binding to specific receptors on neuronal terminals, may initiate a cascade of events that results in an altered state of sensitivity.[79, 86, 87] Specifically, these inflammatory mediators can depolarize primary afferents directly by activating sodium ion channels, though in most cases they sensitize the nerve terminal (ie, lower the threshold for activation) rather than directly activating it.[76, 88] Furthermore, glial cells (ie, Schwann cells, microglia, astrocytes, and oligodendrocytes), are now known to play a key role in the initiation and maintenance of increased nociception following peripheral tissue injury.[89, 90] Under normal conditions, glial cells are quiescent.76 However, upon activation by tissue damage or inflammation, glial cells are capable of releasing a variety of nociceptive sensitizing agents, such as TNF-α,[90] interleukin (IL)-1,[90] nitric oxide,[90] arachadonic acid,[91] and excitatory amino acids,[92] which directly increase nerve excitability, indicating a role for these cells in the initiation and maintenance of enhanced pain states, including neuropathic pain.[93, 94] Sensory nerve gene expression following an inflammatory response can also augment peripheral nociceptive afferent activation.[95] These alterations amplify input to the spinal cord, creating an increased state of excitability and increased sensitivity to nociceptive input (peripheral sensitization).[95, 96]

Neurons in the CNS may also undergo changes that increase their excitability, often as a result of continued impulse activity in the periphery, a situation known as "central sensitization."[85, 97] Activation of the NMDA receptor plays a key role in increasing CNS excitability.[76, 85, 98] During central sensitization, phosphorylation of NMDA receptors causes their translocation from intracellular stores to the synaptic membrane and increases their responsiveness to the excitatory neurotransmitter glutamate.[76] This activity-induced central hyperexcitability causes activation of pain pathways by stimuli that are normally subthreshold (allodynia pain occurring upon normally non-painful stimulation) or cause exaggerated responses to normally suprathreshold stimuli (hyperalgesia greater than normal pain is experienced following a normally painful stimulus).[76, 85]

To counteract pain facilitatory input, activation of descending pain suppression pathways can either reduce the likelihood that a stimulus is perceived as painful or reduce the perceived intensity of pain. Endogenous opioids are one of the key mediators involved in the descending inhibitory pathways and are released in a variety of locations throughout the CNS,

where they can inhibit pain signal transmission. Structures in the midbrain, including the periaquiductal grey, send projections to the spinal dorsal horn that modulate nociceptive neuronal activity through release of endogenous opioids.[99]

Nonopioid processes mediated by monoaminergic neurotransmitters such as norepinephrine, serotonin, and dopamine modulate pain signaling within the dorsal horn, although some of these neurotransmitters can exert either antinociceptive or pronociceptive effects, depending upon the subtype and location of the receptors involved.[78] Descending serotonergic pathways can inhibit nociceptive signaling via 5-HT_1 receptor activation. Specifically, activation of 5-HT_{1A} receptors inhibits the excitability of spinothalamic projecting neurons and excitatory (ie, pain facilitatory) interneurons.[78] Similarly, 5-$HT_{1B/D}$ receptor activation is antinociceptive through inhibition of neurotransmitter release from primary nociceptive afferents.[78] In contrast, descending serotonergic pathway activation can promote nociceptive transmission by activating 5-$HT_{2/3}$ neurons.[78, 100]

Similar to serotonergic pathways, activation of centrally located descending dopaminergic pathways can either inhibit or facilitate nociceptive signaling. Descending dopaminergic pathways inhibit nociceptive signaling by activating D2 and D3 receptors on primary nociceptive afferents and neurons in the dorsal horn, thus inhibiting presynaptic neurotransmitter release.[78, 101, 102] However, dopamine can be pronociceptive if it activates D1 spinothalamic projecting (ie, ascending) neurons.[102]

In contrast to serotonergic and dopaminergic receptor-mediated activity, each of which have pro- and antinociceptive effects, descending noradrenergic pathway activation is only known to have antinociceptive effects.[4] Descending noradrenergic pathways projecting to the spinal dorsal horn originate from several areas within the pontine region of the brain, and inhibit pain signaling by activating α_{2A} receptors on terminals of primary nociceptors, or by activating postsynaptic α_1 receptors, causing release of inhibitory neurotransmitters gamma aminobutyric acid (GABA) or glycine from inhibitory interneurons.[78]

Elucidation of the above mechanisms is helping to shape the manner in which we classify as well as treat acute and chronic pain. In the past, pain has been classified into "simple" categories such as nociceptive, inflammatory, and neuropathic; however, increasingly we have recognized that this may be an oversimplification.

Clinical Examples of Mixed Pain States

How does the information provided above translate into clinical practice? I believe that translation of such occurs in several ways. First is the recognition that acute painful conditions, often associated with acute nociceptive and acute inflammatory mechanisms, may transition to a chronic condition in which more neuropathic mechanisms may ultimately predominate. Such conditions would include acute postmastectomy or postthoracotomy pain transitioning to chronic postmastectomy or chronic postthoracotomy pain as well as pain associated with acute herpetic neuralgia transitioning to chronic postherpetic neuralgia.

Second is the recognition that quite often individuals may experience chronic pain due to more than one painful condition. For example, consider the 55-year-old male with both chronic osteoarthritis-related pain as well as chronic pain as a consequence of his painful diabetic neuropathy. In this instance, his osteoarthritis-related pain is likely to be associated with more inflammatory and nociceptive mechanisms and his diabetic neuropathy-related pain is more likely to be associated with neuropathic pain mechanisms; thus, his chronic pain is associated with mixed pain.

Third is the recognition that certain pain syndromes themselves may be

consequent to multiple distinct mechanisms and thus are associated with mixed pain. An example of such would be pain secondary to an acute lumbar radiculopathy caused by an acute disc herniation and nerve root compression. In this instance, inflammatory and neuropathic mechanisms would likely be contributing to the pain.

In conclusion, our increasing awareness of multiple pain mechanisms has also led to our recognition that quite often mixed pain states and mixed pain mechanisms underlie a patient's chronic pain complaints. This in turn has led to our increasing use of multimodal therapies in the management of such conditions since different pharmacologic as well as nonpharmacologic interventions may have distinct mechanisms of action.

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Use of Opioid Analgesics in Pain Management

by **Keith Candiotti, MD**

Expert authors received compensation from Janssen Pharmaceuticals, Inc. for their contributions to PrescribeResponsibly.com

History

Opioid analgesics have been used as medicinal agents, especially for the treatment of acute and chronic pain, for thousands of years. Ancient Greeks first identified and used these medicines, which were originally derived from opium — the latex of immature seed capsules of the poppy flower (Papaver somniferum).[5,6] From these simple beginnings, opioid analgesics have become a mainstay of medical therapy used by millions of patients each year.[7] While numerous drugs have been developed for the treatment of different types of pain, no single class of agent has replaced or reached the same level of usefulness for the treatment of moderate to severe pain as have opioid analgesics.[8]

Use of Opioid Analgesics in Pain Management

Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[8]

While practitioners often express concern about the use of opioid analgesics for acute and chronic pain conditions, they are often the only suitable agent to control significant pain. This is especially true in the postoperative period.[60] Morphine is the most commonly used opioid analgesic in the postoperative period, but some practitioners prefer other agents, such as hydromorphone.[9] There is some debate as to whether hydromorphone is better tolerated than morphine in terms of side effects. Some recent studies, however, do not support this concept and adverse reactions to either drug are possible.[9]

Another area of debate concerning opioid analgesics is their use in the treatment of neuropathic pain. This area is still being explored and remains somewhat controversial. Most studies related to this question have been

small, demonstrated equivocal results, and have failed to clearly establish the long-term risk/benefit ratio of these agents.[10] A recent Cochrane Review found that the results were somewhat mixed; short-term trials had contradictory results, while intermediate trials demonstrated opioid analgesic efficacy for spontaneous neuropathic pain. Across trials, the side effects were nausea, constipation, dizziness, and drowsiness.[10]

Mechanism of Action of Opioid Analgesics

Opioid analgesics bind to a number of different receptors throughout the body—mu, delta, and kappa.[8] The binding to these different receptors results in both the therapeutic and adverse effects of opioid analgesics. Genetic variations in the structure of these receptors can partially explain interindividual responses, including some adverse reactions to these agents.[11]

Adverse Reactions to Opioid Analgesics

Adverse reactions to opioid analgesics can be a limiting factor in the effective use of these drugs. In a study of patients taking opioid analgesics for prolonged periods of time, 80 percent of patients reported at least 1 adverse event, and 24 percent of patients discontinued therapy due to an adverse event.[12] Evaluation of the discontinuations due to adverse events demonstrated that constipation (41 percent), nausea (32 percent), vomiting (15 percent), and somnolence (29 percent) were the most common reasons cited for cessation of therapy.[12]

Early cessation or limitation of pain treatment due to adverse reactions can result in the inadequate treatment of pain. While more than just an inconvenience, the consequences of inadequate pain control can be far reaching and often are overlooked. Patients experiencing significant pain will have an increase in autonomic and sympathetic activity.[3] Older patients, in particular, may develop delirium and cognitive dysfunction.[13] The intensity of pain in the preoperative, interaoperative and early postoperative periods have been shown to be strong predictors for the development of chronic, persistent postoperative pain.[14] While there are reports that excessive use of opioid analgesics may lead to a state of hyperalgesia,[5] thus prompting some physicians to be concerned about using opioid analgesics for pain control, the lack of sufficient pain control may itself promote a hyperalgesic state in the form of persistent pain.[3]

Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

Conclusion

To date, no agents have fully replaced opioid analgesics for the treatment of moderate to severe pain. While many patients and physicians have concerns about the use of opioid analgesics, which often prevent their use, it would appear that, with appropriate dosing and titration, they can be effective and safe medications for the treatment of painful conditions. In spite of how long these agents have been in clinical use, there still remains much to be learned, and ongoing research will no doubt help clarify some of these questions.

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Risks and Benefits of Opioid Analgesics

This Web site discusses the appropriate use of opioid analgesics to treat patients who are experiencing moderate to severe pain.

Opioids have an important role in the treatment of some types of acute and chronic pain. Opioids, which exert their pharmacologic effects by acting as agonists at different types of opioid receptors in the body, can result in beneficial therapeutic effects, as well as in adverse events in some cases.

Clinicians need to fully weigh the anticipated benefits of opioid therapy with the possibility of adverse events, particularly in patients who have medical conditions or co-morbidities that may put them at increased risk.

Adverse Events and Other Considerations

Common adverse events of opioids include sedation, confusion, nausea, vomiting, constipation, pruritus (itching), respiratory depression, and urinary retention. In general, a proactive, "pre-emptive" approach to managing adverse effects, in particular those related to bowel function, is preferred. With the exception of constipation, these side effects generally subside over time with continued use of the medication. Opioids should always be used cautiously in patients who have impaired ventilation, bronchial asthma, liver failure, or increased intracranial pressure.[3]

Physical dependence with long-term use of opioids should be expected. It is important to note that physical dependence is not the same as addiction.[20] Physical dependence is a state of physiological adaption manifested by a withdrawal syndrome produced by abrupt discontinuation of a medication, decreasing serum concentrations of the medication, and/or the administration of an antagonist or inhibitor of the medication.[3] Active measures, such as tapering the medicine when it is no longer needed, should be taken to prevent or reduce the physical and emotional manifestations of withdrawal.[20]

Addiction is a primary, chronic neurobiological disease with genetic, psychosocial, and environmental factors that influence its development and manifestation. Addiction is characterized by continued use of a drug despite detrimental effects and self-harm, impaired control over the use of a drug, and preoccupation with the use of a drug for non-therapeutic purposes.[3]

For more information about physical dependence and addiction, as well as other important definitions and terms regarding opioid analgesics, go to

What a Prescriber Should Know Before Writing the First Prescription.

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What a Prescriber Should Know Before Writing the First Prescription

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The Importance of Definitions

Knowing the precise definitions that are listed in Table 1 will allow healthcare professionals to improve their understanding of the interface of pain and addiction and their clinical practice.[19] Confusion between physical dependence and addiction may contribute to the undertreatment of chronic pain.[19]

Physical dependence and addiction can coincide, but physical dependence is neither necessary nor sufficient to make a diagnosis of addiction.[20] Physical dependence is an expected, neuropharmacological adaptation that occurs as a result of chronic exposure to an agonist class of drug.[21] Addiction is a much more complex biobehavioral phenomenon.[19]

Physical dependence is a natural, expected neuroadaptive response that can occur with opioids, alcohol, benzodiazepines, corticosteroids, antidepressants, diabetic agents, cardiac medications, and many other medications used in clinical medicine. Abrupt cessation of these medications can produce a withdrawal syndrome that can include, but is not limited to, nausea, vomiting, diaphoresis, diarrhea, abdominal cramps, seizures, anhedonia, dysphoria, and in some cases, death.[20]

Tolerance is also a natural, expected physiologic response that can occur with exposure to certain classes of drugs, especially alcohol and opioids. The key to this definition is that all other factors remain stable so that only the physiologic response to the drug can be evaluated.[19] In fact, tolerance is neither good nor bad. It occurs at different rates, to different effects in different patients, over time. So while there is relatively rapid tolerance to the cognitive blunting effects of the opioid class of drug, tolerance to the constipating effects of opioids rarely occurs.[21]

Concurrent diagnoses such as addiction or pseudoaddiction can be confirmed only by careful evaluation and rational pharmacotherapeutic

management of the pain. While a diagnosis of addiction is made prospectively over time, a diagnosis of pseudoaddiction is usually made retrospectively. When reasonable limits and boundaries are placed on a patient, and yet he or she continues to step out of bounds, addiction or pseudoaddiction should be considered.[20]

Healthcare professionals with improved understanding of the definitions on the basic scientific and clinical levels will be better able to evaluate and treat patients with chronic pain, with or without the disease of addiction.

Disease of Addiction

The healthcare professional must recognize addiction as a treatable, albeit irreversible, brain disease — that is, a distinct medical condition that may or may not be associated with the patient's pain syndrome.[20] One can treat acute pain in the face of an active addiction; however, the treatment of chronic pain in a patient with an active addiction seldom is successful. The patient must be willing to work a program for both diagnoses. The pain specialist must have a rudimentary knowledge of addiction medicine, and the addiction specialist must understand the basics of pain management.

Drugs of misuse act at local cellular and membrane sites that are within a neurochemical system called the reward and withdrawal pathway.[22] This pathway is in the mesolimbic dopamine system of the primitive brain, and addiction causes a disruption of this pathway. This disruption is mediated via receptor sites and neurotransmitters. Central to this reward and withdrawal pathway is the neurotransmitter dopamine, which has been shown to be relevant not only to drug reward, but to food, drink, sex, and social reward.[23]

One of the most common reasons for relapse of patients with addiction is stress.[22] It stands to reason that if a patient with chronic pain is in recovery from drug or alcohol use, and his or her pain is inadequately treated, the patient may turn to licit or illicit drugs and/or alcohol to anesthetize the pain.

Opioid Agreements

Informed consent is part of an initial evaluation. Healthcare professionals must discuss with, and answer any questions about, the proposed treatment plan, including anticipated benefits and foreseeable risks. Written opioid agreements (OA) facilitate the documentation of informed consent, patient education, and compliance in the management of chronic pain.[24]

A well-written agreement establishes the responsibilities of a healthcare professional to the patient and vice versa. It outlines the treatment plan and documents informed consent. The OA establishes boundaries and consequences for drug misuse or diversion. Noncompliance with the agreement can aid in the diagnosis of the disease of addiction or substance misuse, which would often require a change in the treatment plan. Table 2 delineates the salient points of an OA.[25]

The agreement, whether written and signed or informal, must be part of an environment of care that emphasizes honest and open communication. A practice policy for all patients prescribed opioids to sign a medication management agreement is often a simple and effective way to approach this often uncomfortable issue. The agreement should be reasonable, readable, and flexible.[25]

Conclusion

Before writing the first prescription, the healthcare professional should know the basic definitions and principles common to pain and addiction medicine and establish the boundaries through an opioid agreement.[20,26] Risk can never be eliminated, but it can usually be managed. By approaching these patients within a biopsychosocial framework, the healthcare professional can give the patient the best quality of life possible, given the reality of his or her clinical situation.

TABLE 1: Definitions

1. **Aberrant behavior** is when the patient steps outside the boundaries of the agreed upon treatment plan, which is established as early as possible in the healthcare professional-patient relationship.[20]
2. **Abuse** is any use of an illicit drug with the intentional self-administration of a medication for nonmedical purpose such as altering one's state of consciousness (eg, getting high). A licit substance such as alcohol also can be abused.[27]
3. **Addiction** is a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.[21]
4. **Diversion** is the intentional removal of a medication from legitimate distribution and dispensing channels for illicit sale or distribution.[27]
5. **Iatrogenic addiction** occurs when a patient with a personal or family history of alcohol, drug addiction, or abuse is appropriately prescribed a controlled substance and subsequently in the therapeutic course, meets the diagnostic criteria for addiction to that substance.[25]
6. **Misuse** is use of a medication (for a medical purpose) other than as directed or as indicated, whether willful or unintentional, and whether harm results or not.[27]
7. **Physical dependence** is a state of adaptation that is manifested by a drug-class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.[21]
8. **Pseudoaddiction** is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.[25]
9. **Pseudotolerance** is the need to increase medication such as opioids for pain when other factor(s) are present such as disease progression, new disease, increased physical activity, lack of compliance, change in medication, drug interaction, addiction, and/or deviant behavior.[25]
10. **Tolerance** is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[21]

TABLE 2: Treatment Agreement for Opioid Analgesic Maintenance Therapy for Noncancer/Cancer Pain[25]

- Goals of therapy
- Single prescriber, if possible
- Informed consent on all opioid analgesic risks
- Definition of addiction, tolerance, and physical dependence
- Need for patient disclosure of substance abuse history; psychiatric history including history of sexual, physical, or verbal abuse; and medications currently prescribed
- Need for complete, honest self-report of pain relief, side effects, and function at each medical visit
- Establishment of regular medical visits
- Requirement for prescription renewal only during regular office hours
- Conditions of noncompliance (eg, evidence of drug hoarding or use of any illegal drug may cause termination of the healthcare professional–patient relationship)
- Use of the word *may* instead of *will* in the agreement, so clinical judgment can be used in each situation
- Patient consent to random urine drug tests and pill counts
- Permission for the practice to contact appropriate sources to obtain or provide information about the patient's care or actions
- Recovery program for substance misuse or addiction (patients must agree to concurrent assessment and treatment of their substance use disorder)

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Assessing Patients With Pain and Using Evaluation Tools

by **Kenneth L. Kirsh, PhD**
& **Steven D. Passik, PhD**

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Prescribing opioid analgesics safely hinges on risk stratification and the accommodation of that risk into a treatment plan. Healthcare professionals writing prescriptions for opioid analgesics need to become proficient in performing and documenting a risk assessment. The use of a screening or ongoing assessment tool fulfills the growing requirement for due diligence in screening for the patient's vulnerabilities and risk and incorporating the results into treatment planning. Additionally, the use of validated tools not only helps guide the assessment, but also upgrades the healthcare professional's chart documentation.[28]

Patient Risk Stratification

An assessment of chronic pain should include a detailed assessment of the pain itself, including:

- Intensity, quality, location, and radiation of pain;
- Identification of factors that increase and decrease the pain; and
- Review of the effectiveness of various interventions that have been tried to relieve the pain.

The impact of pain on quality of life (eg, function in work, relationships, and recreational activities; effects on sleep, mood, level of stress) should also be assessed because improvement in these domains may be a goal of pain treatment and a measure of the efficacy of interventions.

Numerous general screening instruments are available to assist in these assessments. Among those used in clinical settings are the Brief Pain Inventory,[3] the Roland Morris Disability Scale,[29] and the 9-item Patient Health Questionnaire (PHQ-9), a brief measure to identify depression,[30] the most common psychiatric problem seen among patients with pain.[31]

While these tools offer good generalized assessment, there has been a need for more focused risk assessment tools to help identify patients who are likely to misuse opioid analgesics. While caution is always warranted regarding interpretation of scores, several tools have emerged as clinically useful.[32] One recommended example is the Opioid Risk Tool (ORT), which

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- NRS
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consists of 5 self-report items that cover issues such as family and personal history of substance abuse, age, history of preadolescent sexual abuse, and psychological disease. Each positive response is given a score based on patient gender, and then the scores are summed into categories of low, moderate, or high risk.[32] The ORT is a very useful tool for healthcare professionals because of its brevity and ease of scoring, but it may be prone to underreporting and deception.[32] Another, slightly more time-intensive example is the Screener and Opioid Assessment for Patients with Pain (SOAPP), which is an accurate tool for assessing abuse potential in patients being considered for opioid analgesic therapy and has good psychometric properties.[32] It consists of 14 items utilizing a 5-point scale (0 = never, to 4 = very often), with a cutoff score of 8 to determine risk. The relatively low cutoff score of 8 was chosen, in part, because individuals who believe that their responses may determine their opioid analgesic treatment may underreport their behavior, and because some patients fear their answers may be misconstrued.[32]

Ongoing Pain Assessment

Performing an initial risk assessment is valuable but also should be followed with some form of ongoing assessment. To perform a comprehensive yet time efficient follow-up, it is important to consider four domains for patients on opioid analgesics. These domains have been labeled the "4 As" (analgesia, activities of daily living, adverse effects, and aberrant drug-related behaviors) for teaching purposes.[33]

To help healthcare professionals use the 4 As clinically, Passik and colleagues created a simple charting device called the Pain Assessment and Documentation Tool (PADT™).[34] The PADT is a two-sided chart note that can be easily included in the patient's medical record and is designed to be intuitive, pragmatic, and adaptable to clinical situations.[34] The value of assessing pain relief, side effects, and aspects of functioning has been emphasized repeatedly in the literature and the PADT acknowledges these standards. Documentation of drug-related behaviors, however, is a relatively new concept that has been incorporated into the PADT.[34]

Patient-Prescriber Communication

Successful outcomes in pain management depend on how well healthcare professionals motivate patients to take responsibility for active participation in their care, and how they use their medications is one aspect of this responsibility. The 4 As described above double as both an ongoing assessment tool as well as an opportunity for interaction. A further opportunity for clear communication involves the use and implementation of opioid agreements.

The Psychology of Opioid Agreements

While opioid agreements and consents are discussed in What A Prescriber Should Know Before Writing the First Prescription, it is important to explore this issue with regard to the psychology and meaning behind them, as well as how they can impact the therapeutic milieu. An opioid agreement (OA) can be nothing more than a piece of paper if it is signed, sealed, and placed in the patient's medical record and never discussed or examined again. Opioid agreements, which often have been incorrectly called "contracts," traditionally have been used only after a patient had a lapse in behavior or judgment that compromised the medicine's clinical value or the trust between the healthcare professional and the patient. At its best, however,an OA can be educational, informative, and even motivational if it helps the patient understand opioid therapy and how it differs from other drug therapies where adherence to the rules of drug-taking are not nearly as emphasized. In addition, they can be helpful in reducing multiple prescribers, preventing abuse, and clarifying goals of treatment.[35]

If a medical practice is to avoid bias and the accusation that they are singling out only the problematic patients, the use of an OA should be practice-wide at the outset of opioid therapy. The agreement should be handed out and introduced as an exercise in mutual trust and goal-setting by the medical

staff. The OA should be introduced and discussed by the healthcare professional, not the clerical staff. In addition, the language in the OA should be flexible; otherwise, the staff is likely to be in violation of its agreement as often as the patient. Healthcare professionals must always remember that violations of the agreement might be due to a range of issues from misunderstanding, pseudoaddiction, chemical coping or more illicit behaviors such as frank abuse or diversion. As such, flexible language in the OA allows the healthcare professional an opportunity to test these hypotheses and determine the true nature and cause of the infraction.

Conclusion

The following are a few best practices for assessment and use of evaluation tools:

- View pain management activities as always involving some level of risk management.
- All good pain management efforts should begin with a proper history and physical exam (ie, documenting source of pain, length of time with condition, aggravating and alleviating factors, and impact on psychosocial functioning).
- Use a known and available general pain tool such as the Brief Pain Inventory to get a global sense of the patient's pain concerns.
- Before an opioid medication is written, use an available predictive risk tool such as the ORT to get a general level of risk burden with a particular patient. (Note: Never use these tools to deny therapy, but do use them to determine level of oversight, which will be required.)
- If opioid therapy is started, be sure to document ongoing therapy goals and the 4 As.
- Use opioid agreements to initiate therapies, and refer back to them at least annually as a point of discussion with the patient.
- Always know your limits and do not be hesitant to make referrals or ask for specialty help (ie, addiction management or behavioral medicine specialists) when treating patients with complex medical and psychosocial issues.

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Philosophy of Urine Drug Testing in Pain Management

by **Howard A. Heit, MD, FACP, FASAM**
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Urine drug testing (UDT) is a useful tool in pain management that provides valuable objective information to assist in diagnostic and therapeutic decision making.[36] Results of a UDT provide confirmation of the agreed-upon treatment plan (adherence/compliance). They can diagnose relapse or drug misuse as early as possible, and they also can be used to advocate for the patient with third-party interests.[37]

To assess compliance, the healthcare professional may look for the presence of prescribed medications in the urine as evidence of their use. Finding no presence of the prescribed drug or finding unprescribed or illicit drugs in the urine merits further discussion with the patient. At the same time, it is important to recognize that laboratory error and test insensitivity can result in misleading data. Bingeing by the patient can result in unexpected negative urine reports if the patient runs out of medication prior to urine sample collection. Therefore, these results by themselves cannot be relied upon to prove drug diversion and may be consistent with addiction, pseudoaddiction, or the use of an opioid for nonpain purposes—so called chemical coping.[36]

The purpose of UDT should be explained to the patient at the initial evaluation. UDT can also enhance the relationship between healthcare professionals and patients by providing documentation of adherence to mutually agreed-upon treatment plans.[36]

In the pain management setting, the presence of an illicit or unprescribed drug does not necessarily negate the legitimacy of the patient's pain complaints, but it may suggest a concurrent disorder such as drug abuse or addiction. The patient must be willing to accept assessment and treatment of both disorders to receive adequate outcomes in either. Thus, the diagnosis of a concurrent addictive disorder, when it exists, does nothing to negate a legitimate pain disorder; rather, it complicates it.[36]

Specimen Choice
Urine has been the preferred biologic specimen for determining the presence

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or absence of most drugs. This is, in part, due to the increased window of detection of 1 to 3 days for most drugs and/or their metabolites.[36] Table 3

Whom to Test and Frequency of Testing

The question of whom to test is made easier by having a uniform practice policy either in a pain or primary practice that would help reduce individual stigma. Any risk of patient profiling based on racial, cultural, or other physical appearances is eliminated. Careful explanation of the purpose of testing normally allays patient concerns.[36]

Healthcare professionals sometime find the subject of drug testing a difficult one to explore with their patients, especially those who have been in the practice for many years. Often, a healthcare professional's perception is that requesting a urine sample for drug testing may be seen as mistrusting the patient and, consequently, potentially damaging to the healthcare professional-patient relationship. In fact, when approached in a respectful, patient-centered fashion, most patients are more than willing to do their part in managing risk in order to receive the care that they need.

Testing Strategies

The healthcare professional must know the drugs for which to test, appropriate methods to use, and the expected use of the results obtained.[36] Immunoassay drug tests are most commonly used. They are designed to classify substances as either present or absent and are generally highly sensitive. In pain management, specific drug identification using more sophisticated identification tests is needed.[36] Techniques such as Gas Chromatography/Mass Spectroscopy (GC/MS) and High Performance Liquid Chromatography (HPLC) are used for the identification of a specific drug and/or its metabolites.[36]

Immunoassay drug tests for natural opiates are very responsive to morphine and codeine, but do not distinguish between the two. UDT by immunoassay also shows a low sensitivity for semisynthetic/synthetic opioids such as oxycodone and fentanyl.[36] Even though an immunoassay may be negative for consumed oxycodone, it should be positive on GC/MS if the drug was used within the window of detection. The clinical importance of this fact with UDT cannot be overstated, because compliant patients may have been dismissed from pain management practices secondary to a false-negative immunoassay test when looking specifically for prescribed oxycodone.[36] Specific drug identification by chromatographic testing (ie, GC/MS) also is necessary to identify which member of the detected class is responsible for the positive screen.[36] Drug-specific immunoassays presently on the market and under development will identify semisynthetic/synthetic opioids.[37] The healthcare professional should always know the limits of the UDT ordered.[37]

A routine UDT screening panel suggested for the following drugs/drug classes is listed in Table 4.[36]

Healthcare professionals also must understand the basic metabolism of commonly prescribed drugs, especially opioids, so they will be able to explain a UDT result that is positive for the prescribed medication and/or its metabolite(s). Figure 1[37]

Dealing With Unexpected Urine Toxicology Results

UDT in clinical practice must be used to improve patient care. Unfortunately, these test results may come back unexpectedly negative for a prescribed drug or positive for an unprescribed one. The first step in interpreting these results is to contact the lab to ensure that no clerical errors have been made.[37] If unexpected results are confirmed, there must be a process in place that should include discussing the unexpected result with the patient.[36]

Conclusion

UDT is an effective tool in the assessment and ongoing management of patients who will be, or are being, treated chronically with controlled

substances. Most importantly, a healthcare professional should have a relationship of mutual honesty and trust with the patient when using UDT in the clinical practice, as well as maintain open communication with the testing laboratory. The use of UDT should be consensual; it is designed to improve patient care and to assist the healthcare professional to advocate on the patient's behalf.[36]

TABLE 3: Windows of Detection in Urine Drug Testing[36]

Drug	Approximate Retention Time
Amphetamines	48 hours
Barbiturates	Short acting (eg, secobarbital): 24 hours Long acting (eg, phenobarbital): 2-3 weeks
Benzodiazepines	3 days, if therapeutic dose is ingested Up to 4-6 weeks after extended dosage (ie, 1 or more years)
Cocaine Metabolite	2-4 days
Ethanol	2-4 hours
Methadone	Approximately 3 days
Opiates	2 days
Propoxyphene	6-48 hours
Cannabinoids	Moderate smoker (4 times/week): 5 days Heavy smoker (smoking daily): 10 days Retention time for chronic smokers may be 20-28 days
Phencyclidine	Approximately 8 days Chronic users: up to 30 days (mean value = 14 days)

Note: Interpretation of retention time must take into account variability of urine specimens, drug metabolism and half-life, patient's physical condition, fluid intake, and method and frequency of ingestion. These are general guidelines only.

TABLE 4: Suggested Screening Panel[36]

A routine UDT screening panel should test for the following drugs/drug classes:

- Cocaine
- Amphetamines/Methamphetamine
- Opioids
- Methadone
- Marijuana
- Benzodiazepines

FIGURE 1. Metabolism of Opioids[37]

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Pain Management Practice Assessment

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Pain and addiction can, and sometimes do, coexist.[20] In the average family practice, the prevalence of a substance use disorder is at least that of the general population.[38] One challenging question in assessing and managing risk in any medical practice is determining what proportion of the practice represents higher risk. For example, the prevalence of substance use disorders in the general population is 3 to 16 percent, with 10 percent being commonly reported in the pain management literature.[20] In a primary care setting with a special focus on pain management, this number would be expected to increase. In practices limited to the assessment and management of individuals with concurrent pain and substance use disorders, the prevalence approaches 100 percent. Clearly, each practice will have differing needs with respect to risk assessment and management.

Knowing Your Practice

Knowing your limits in patient selection is a fundamental challenge in medicine in general, and in primary care in particular. Just as not all patients can be safely managed in the primary care setting, not all challenging cases need or necessarily can be transferred to specialty care. Of course, sometimes the risk posed by certain patients exceeds the experience and resources available to that primary care physician, and so the risk of these patients must be managed either through treatment of their concurrent substance use disorder, or by limiting the pharmacologic treatment options.[28]

Knowing Your Patients

In the treatment of chronic pain, it is important to establish reasonable therapeutic goals from the outset. It is rare that "pain free" or "to be cured" are reasonable goals for patients with chronic pain. Many patients have come to significant harm in a misplaced attempt to achieve a cure for their condition. While it is reasonable to expect to reduce pain scores and often improve function, there must be a constant balancing of risk and benefit in determining success or failure in any therapeutic trial. This is especially true with opioids.[39]

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It is not uncommon for patients to share concern and, in some cases, fear about the use of a controlled substance. Although it is true that the majority of those who use prescription opioids for the treatment of pain do not become addicted,[20] some fail to respond as expected, and a small number may engage in problematic behavior. In these cases, it is important to have a clearly defined "exit strategy" for discontinuation of the opioid class of drugs. Some patients may easily discontinue the use of opioids when it becomes apparent they are no longer serving a useful purpose, but most require a careful taper. Still others will require the assistance of those more experienced in withdrawal management.[20]

Physical dependence is neither necessary nor sufficient to define addiction.[20] The fact that a patient may struggle to discontinue prescription medications, especially toward the end of the taper is no reflection on the presence or absence of a concurrent substance use disorder. A commonly recommended taper schedule is to reduce the medication by 10 percent every 1 to 2 weeks until the bottom 20 percent is reached, at which point the drop is reduced to 5 percent and the interval increased to every 2 to 4 weeks.[20] This reflects the fact that for most patients, the more challenging point is the bottom of the taper. It is important to ensure that during the taper, medications of a similar class of drug are not inadvertently substituted for the drug being tapered. This is commonly seen in the patient who "successfully" stops drinking alcohol only to substitute his or her drug of choice through the chronic use of benzodiazepines.

In those cases when a patient expresses concern about addiction, it is important to have an open and nonjudgmental discussion. While the patient's initial concern may appear to be physical dependence and may require reassurance from the healthcare professional, it can be useful to probe more deeply. There may be more to the patient's concerns than originally stated. Aberrant behavior is an often late and unreliable sign of addiction. Addiction remains a diagnosis that is best made prospectively over time. On the other hand, pseudoaddiction is a diagnosis made retrospectively.[20] Aberrant behavior that normalizes with more effective management of pain confirms this diagnosis.

Conclusion

By taking time to carefully assess the actual risk associated with your practice, you can optimize patient care while reducing the potential harm to you and others.

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Diversity of Patients

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Pain management is a complex endeavor even for patients with few comorbidities. Developing algorithms or "cookie cutter" approaches to pain management remains ineffective in even the uncomplicated cases due to variable responses in metabolism, neuroreceptor profiles, and variations in side effect profiles and tolerability. Many patients, however, have significant issues that affect their lives, which create a more complex scenario.

Patients roughly fall into 3 camps of complexity: low, moderate, and high. Where they fall on this spectrum depends on the involvement of issues such as abuse, addiction, medical comorbidities, psychiatric issues, past functional history, and the number of pain complaints. This section provides a series of brief examples that are commonly seen when caring for patients with pain.

Special Populations: Catastrophizing

The term "pain catastrophizing" refers to a patient's core belief that his or her pain is awful, unbearable, and horrible.[40] One of the most robust findings in recent psychological pain research is the role of pain catastrophizing in exacerbating the experience of pain. Medical literature defines pain catastrophizing in many different ways, but usually includes a tendency for the patient to ruminate about the pain condition, magnify or exaggerate the meaning of the pain for daily functioning, and feel helpless to manage the pain.[41]

Empirical studies demonstrate that higher levels of pain catastrophizing are associated with increased pain sensitivity and emotional distress, and this impact is present and significant even when controlling for other variables such as pain severity, depression, anxiety, and fear of pain.[40,42] There is no doubt that living in such an emotionally charged state would have a definite impact on the overall functioning of patients with pain; however, it is not always evident which patients are most likely to fall into this category. For this reason, having a screening tool available to give an indication of whether a patient is engaged in catastrophizing can be extremely helpful for healthcare professionals.

While several scales have been created to measure catastrophizing, the Pain Catastrophizing Scale has received the most attention and has proven

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to have stable test-retest reliability.[41] Once pain catastrophizing has been identified, it is usually best to seek consultation to help the patient engage in cognitive restructuring to reduce disability and pain severity and improve mood.

Chemical Coping

There is a vast middle ground between generally compliant drug-taking behavior and frequent or severe aberrant behaviors that are likely to be associated with addiction. A large group of patients in the middle fall between these two ends of the spectrum — those who display aberrant behaviors periodically and may have a mixed response to opioid therapy. While most research focuses on the prediction, assessment, and treatment of substance use disorders, little attention has been paid to this group of patients.[43] Some of these patients may be termed "chemical copers."

Palliative care specialist, Eduardo Bruera, MD, and colleagues coined the term "chemical coping" to describe a pattern of maladaptive coping through drug use that they observed in patients struggling with the stress of end-stage cancer.[43] Building on this notion, Kenneth Kirsh, PhD, and colleagues adapted the notion to patients with pain, in general, and ultimately developed a scale to detect chemical coping. It is important, however, to understand the current definition of this phenomenon.[43]

Simply put, chemical copers occasionally use their medications in nonprescribed ways to deal with stress. For these patients, medication use becomes central to life, while other interests become less important. As a result, chemical copers in treatment often fail to move forward toward stated psychosocial goals. They are typically uninterested in treating pain or coping with pain nonpharmacologically and do not take advantage of other treatment options provided (eg, fail to follow up on recommendations to see psychologists or physical therapists). As a manifestation of chemical coping, these patients remain on the fringe of appropriate use of their medication. They occasionally self-escalate their medication dosage in times of stress and sometimes need to have prescriptions refilled early.[43]

Chemical coping can complicate opioid therapy, but many chemical copers are able to comply with their physician's opioid agreement enough to avoid being removed from treatment.[43]

Best Practice Suggestions With the Chemical Coper:[43]

- Whenever possible, simplify drug regimens (ie, prescribe longer-acting medications to reduce overall number of pills available to a patient at any one time).
- Decentralize opioid use in these patients (ie, always reinforce that opioids are part of the full regimen and not the sole focus).
- Encourage or require psychotherapy and other adjunctive modalities to be part of the treatment approach.
- Focus on teaching coping strategies as alternate choices to reaching for a pill bottle in times of stress or emotional upset.

Comorbidity Issues: Depression

The notions of pain catastrophizing or chemical coping are important, but neither truly rises to the level of a unique comorbid condition when discussing patients with pain. On that front, the most frequent comorbid condition seen with pain is major depression.[31] Whether depression is premorbid or manifested as a result of the pain condition, the burdens of coexisting pain and depression should not be ignored. Although there is more work to be done, there has been enormous progress in understanding, assessing, evaluating, and treating these patients.

The overlap of pain and depression is seen in 30 to 60 percent of patients.[44] Research has also shown that the more severe, frequent, and enduring the painful condition, the more severe any corresponding depression will be.[45] Further, patients with more severe levels of depression have a tendency toward establishing less realistic goals and less acceptance of their condition, thus creating a cycle of hopelessness that exacerbates their pain

condition.[44] Finally, some research proposes two facets that may mediate the effects of pain and depression: a patient's perspective on the role of pain in his or her life and the ability to maintain control over the pain and life, in general.[46] Thus, the more perceived control a patient believes he or she has in life, and the smaller role that pain is allowed to play, the less likely the patient will become depressed.[47]

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Genetics and Pain

by **Keith Candiotti, MD**

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Anyone who has ever cared for patients who are injured or in pain has noted the marked degree of variability in pain responses from patient to patient. Large differences in reported pain levels are ubiquitous, with this effect being noted for both consistent tissue injuries (eg, surgery) as well as less defined systemic diseases or unknown causes (eg, fibromyalgia).[48] In medicine, healthcare professionals traditionally are taught to treat all patients in the same manner. This approach may, in fact, be harmful to many. Differences in pain tolerance and response to pain medications are partially, but significantly, linked to a patient's genetic makeup. Without considering these factors, it is easy to either undertreat or overtreat a patient. Currently, it is unusual for a physician to know anything about a patient's genetic makeup. A patient's medical and family history and ethnicity, however, may often hold useful clues concerning this area.

Genes and Pain Response

The pain response is complex. The final resulting pain experience occurs as a product of many factors, including genetic composition, prior experience, physiological status, appraisals and expectations, mood, behavioral repertoire of pain-coping skills, and sociocultural background.[49] Which factors, and to what extent they have an impact on the final behavior of a patient, is an area of considerable controversy.

Many genes and their polymorphic variants appear to affect the pain response. Only a few of them, however, have been studied, and some of the trials have produced conflicting results.[50] Some genes that have been shown to have a statistically significant pharmacogenetic modulation on the therapeutic effects of opioid analgesics include μ-opioid receptor (OPRM1); catechol-O-methyl transferase (COMT); melanocortin-1 receptor (MC1R); cytochrome P450 2D6 (CYP2D6); ATP, binding cassette, B1 (ABCB1); and interleukin receptor antagonist.[50] The degree that each of these genes affects the pain response is still unclear, but it is apparent that they can play a significant role.

Advances and the Future of Pain Genomics

While many factors produce the pain phenotype, the role of heritability is apparently more significant than previously thought. As research progresses and more data become available, the degree of genetic contribution will no

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doubt become clearer. A decade ago, the field of pain genomics was basically unknown, but today the area is rapidly advancing with new information and data appearing in the literature on a regular basis. As our understanding of the heritability of the pain phenotype increases, new treatment options may become apparent as well.

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Dr. Argoff has served as a guest editor and published articles in the *Clinical Journal of Pain* and *Current Pain* and *Headache Reports*, among other peer-reviewed journals. He has written on many types of pain, including myofascial pain, spinal and radicular pain, and neuropathic pain. He has written on such treatments as topical analgesics, interventional pain management, botulinum toxins, the scientific basis of multimodal therapy for chronic painful conditions and oral analgesics, and has contributed many book chapters as well. Dr. Argoff had an active role in the development of the diabetic peripheral neuropathic pain guidelines published in *Mayo Clinic Proceedings*, and he has contributed to other published neuropathic pain treatment guidelines. He is one of the editors of the published textbook *Raj's Practical Management of Pain*, Fourth Edition. He is the co-author of *Defeat Chronic Pain Now*, a book for people with chronic pain. He also has recently published the third edition of *Pain Management Secrets*.

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Dr. Candiotti has published numerous articles and abstracts at various medical meetings. He currently lectures both in the United States and around the world on topics related to his areas of interest.

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His practice encompasses the assessment and treatment of patients suffering from pain and addiction, as well as general addiction medicine. He is currently the Director of the Pain and Chemical Dependency division of the Wasser Pain Management Centre at Mount Sinai Hospital in Toronto as well as the former Clinical Director of Laboratory Services at the Centre for Addiction and Mental Health. Dr. Gourlay is also diplomate in addiction medicine by the American Board of Addiction Medicine.

Dr. Gourlay is active in various educational and policy initiatives, both provincially and nationally in Canada, and in the United States.

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Dr. Heit was cosection coordinator, author, and an editor on "Pain Management and Addiction Medicine" for the second and third edition of ASAM's textbook Principles of Addiction Medicine. He also coauthored two chapters in the fourth edition of Bonica's Management of Pain. Dr. Heit served as chair of ASAM's scientific program "Common Threads: Pain and Addiction" from 2000 to 2005.

Dr. Heit is a founding board member and treasurer of the International Association for Pain and Chemical Dependency. He is the recipient of the Marie Nyswander Award, which is given at the International Pain and Chemical Dependency Conference to an individual who has helped to build a bridge between pain and addiction and who has been a spokesperson for the compassionate and humane treatment of patients with pain.

Dr. Heit was also instrumental in forming the Liaison Committee on Pain and Addiction of the American Society of Addiction Medicine, the American Academy of Pain Medicine, and the American Pain Society. The mission of this committee is to encourage collaboration between pain specialists and addiction specialists on issues of common interest.

From 1990 to 1996, Dr. Heit served as medical addictionologist for Alcohol and Drug Services for Fairfax County in Virginia.

Dr. Heit is an assistant clinical professor of medicine at Georgetown University School of Medicine. He has lectured and published extensively on the interface of pain and addiction medicine.

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Dr. Kirsh is a graduate of Indiana University-Purdue University, Indianapolis, where he received his doctorate degree in clinical rehabilitation psychology. He completed a psychology internship at the Louis Stokes Cleveland Veterans Affairs Medical Center in Cleveland, Ohio, and worked at hospitals and other facilities including the Indiana Women's Prison.

Dr. Kirsh is a member of the Kentucky Pain Initiative and the PDQ Supportive and Palliative Care Editorial Board, and he has chaired both the Clinical Care Research Team for Supportive Care and the Symptom Management and Palliative Care Research Council at the University of Kentucky. He has published more than 40 articles and twelve book chapters on assessing and managing pain and has received many honors and awards in recognition of his achievements. In 2006, Dr. Kirsh was named a National Institutes of Health Building Interdisciplinary Research Careers in Women's Health program scholar.

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Dr. Passik has served on the editorial board of the Journal of Pain and Symptom Management and has been a reviewer for the Journal of Pharmaceutical Care in Pain and Symptom Control, Journal of Pain and Symptom Management, Psycho-Oncology, Cancer Investigation, Oncology, and Agency for Healthcare Research and Quality cancer pain guidelines, Dr. Passik has served as the president of the Indiana Cancer and AIDS Pain Initiative and as editor in chief of the National Cancer Institute's PDQ Supportive Care Editorial Board.

He is the author of more than 113 journal articles, 55 book chapters, and 59 abstracts. He was recently named a Fellow of DIV 28 of the American Psychological Association (Psychopharmacology and Substance Abuse), awarded a Mayday Fund Pain and Society Fellowship, and was also given the Academy of Psychosomatic Medicine 2007 Visiting Professor Award. Dr. Passik serves on the Advisory Board for the American Psycho-Oncology Excellence in Clinical Care Award, which he was awarded in 2007; and in 2008, at the American Pain Society meetings, Dr. Passik received the Elizabeth Narcessian Award for Outstanding Educational Achievements.

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Treating Mixed Pain

by **Charles E. Argoff, MD**

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Case Study Profile

- Treating mixed pain
- Male
- Age 54

Situation Overview

You are seeing a 54-year-old male in your office whose chief complaint is of increasingly severe low back, bilateral knee and foot pain as well as numbness in both feet. His symptoms have been present for 3 months and are not associated with any particular event or trauma.

Scenario

His past medical history is notable for Type 2 Diabetes Mellitus known for six years, hyperlipidemia, and hypertension. In addition, he has experienced occasional nondisabling episodes of low back pain since his mid-30s and regularly exercises and stretches as part of his daily regimen. An MRI examination of his lumbo-sacral spine done 4 years ago had demonstrated multilevel degenerative joint changes, disc desiccation at the L3-4, L4-5, and L5-S1 levels but no specific disc herniations or nerve root impingement. It had been ordered by an orthopedist who subsequently recommended therapeutic exercise as a treatment. He notes as well that recently his balance is "off" and that he feels burning in his feet.

Current medications include: lovastatin, metformin, enalapril, and occasional use of ibuprofen, naproxen, or acetaminophen.

Upon examining him, you note that his blood pressure is 130/80mm Hg, HR: 72, RR: 16 Pain level: 6/10 and his BMI is 21. His general examination is otherwise unremarkable and peripheral pulses are present. Straight leg raising is negative but there is restriction of forward flexion of the lumbar spine due to increased pain, and his lower back is generally tender to palpation. Neurological examination reveals that he is alert and fully oriented with higher cortical functions intact. There are no cranial nerve deficits and his strength is full in all extremities. His sensory examination reveals diminished pin prick to the calves bilaterally, and impaired vibratory and position sense in both distal lower extremities. Monofilament testing also confirms sensory abnormalities in his distal lower extremities. His deep

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tendon reflexes are intact in the upper extremities and at both knees, but his ankle jerks are trace present. There are no carotid bruits noted by auscultation.

Key Learning

How does this examination help you to understand the possible etiology(ies) of his current pain complaints?

The diagnosis of chronic spinal degenerative disease has already been established. What is demonstrated on examination are new findings that are consistent with a peripheral neuropathic process. Given his history of type 2 diabetes mellitus, you suspect that he has developed a peripheral neuropathy associated with diabetes and further testing is considered, including blood work to rule out nondiabetic etiologies to his apparent neuropathy as well as electrophysiologic testing. You arrange for such testing, including an EMG/NCV of the lower extremities and blood work, and the results demonstrate a sensorimotor symmetric peripheral neuropathy, no other medical condition that would cause neuropathy other than his known type 2 diabetes mellitus and, a Hemoglobin A1C of 7.5 percent. You counsel him regarding optimizing his diabetes treatment and discuss the etiologies of his current pain complaints with him.

Application

The above represents an instance of mixed pain. Although he has a known history of a non-neuropathic type of chronic pain condition-nonradicular chronic low back pain associated with spinal degenerative changes, he has developed a neuropathic pain condition, eg, painful diabetic neuropathy. Recognizing that he is experiencing mixed pain types is vital for optimizing treatment. Pharmacologic approaches typically effective for non-neuropathic pain such as nonsteroidal anti-inflammatory drugs (NSAIDS) are not typically effective for neuropathic pain conditions such as painful diabetic neuropathy. Certain pharmacologic agents such as opioids and serotonin-norepinephrine reuptake inhibitor (SNRI) agents may be effective for both.

Assessment of the Patient with Pain

by **Kenneth L. Kirsh, PhD**
& **Steven D. Passik, PhD**

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Case Study Profile

- Assessment of complicated issues in a patient with cancer pain
- Male
- Age 54

Situation Overview

As part of responsible opioid prescribing, it is imperative that some risk stratification and ongoing assessment be used when prescribing opioid therapy. Simply adopting one of the measures available to healthcare professionals and applying it without clinical judgment, however, is problematic. Rather, assessment tools should be combined with clinical judgment as well as other objective measures, such as urine screens, to arrive at a plan of care and overall risk management.

Certain behaviors observed in people who abuse pain medicines are obviously aberrant. Aberrant behavior is when the patient steps outside the boundaries of the agreed upon treatment plan, which is established as early as possible in the healthcare professional-patient relationship. Examples of the more obvious aberrant behaviors include intravenous injection of oral formulations and concurrent use of related illegal drugs. Other behaviors, however, are less blatant. It is important to recognize that these, more subtle behaviors — for example, aggressively requesting medication or unsanctioned dosage escalations — are not necessarily an indicator of an opioid addiction and may be the result of a patient experiencing unrelieved pain. [1]

The case below highlights the issues that can arise when using risk assessment tools. While this case discusses a patient with cancer pain, many of the issues translate to patients with non-cancer-related pain and can be applied to that population as well.

Scenario

Mr. JT, a 54-year-old patient, is introduced to an ambulatory palliative care service after a diagnosis of end-stage pancreatic cancer. The initial intake reveals that he has a significant history of drug use and criminal activity. His

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Opioid Risk Tool (ORT) score places him firmly in a high-risk category, indicating that caution will likely be needed when prescribing opioid analgesics. Given his poor prognosis, the patient is placed into hospice care. Hospice staff become increasingly worried when they observe that the patient often appears overly sedated, complains of increasing pain, and runs out of medications early. Assessment using the Pain Assessment and Documentation Tool (PADT™) on an ongoing basis shows the appearance of aberrant behaviors coupled with a failure to improve any functioning. The patient is considered for discharge from hospice after his aberrant behaviors continue and his lack of response to the prescribed medication regimen does not improve.

The hospice staff is able to gain his confidence and learn that the patient's son, who also has a criminal history, has been stealing his pain medications and sedating him with promethazine. When the hospice staff asks him why he did not tell them sooner, the patient says that he didn't want to get his son into trouble. The patient's home situation is adjusted, and the patient is able to stay in hospice and achieve adequate pain care.

Key Learning

This case demonstrates that proper assessment is a necessary but not comprehensive part of pain management. Based upon the ORT scores and PADT findings alone, Mr. JT would be identified as having aberrant behaviors, and the likelihood of him abusing or diverting his medications would be considered. His ORT correctly classified him as high risk, which would place him in a category requiring close supervision (but this does not mean he should be denied treatment). The ongoing PADT results showed failure to improve functioning (which should occur even in patients with cancer, but with an obvious sliding scale with regard to what designates improved function), as well as what appeared to be aberrant behaviors (eg, overly sedated, running out of medications early, among others). A third variable, however, namely his son with a criminal background, was actually the causative factor behind the problems.

How would this case differ if Mr. JT had been a patient with severe low-back pain? If he had exhibited a similar constellation of behaviors, would you have responded differently?

Application

When considering opioid analgesic therapy as a form of treatment for pain, healthcare professionals must recognize the need to do a thorough workup and physical exam, including some level of risk stratification and ongoing assessment. There is no "cookie cutter" approach, however, to pain management, and we must therefore remember that the tools available to us should not be used on their own to determine eligibility. Clinical judgment will still be needed to assess all of the findings and to develop an appropriate and cohesive treatment plan for each patient with pain.

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Treating Acute Pain

by **Keith Candiotti, MD**

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Case Study Profile

- Treating an elderly patient with a recent knee replacement
- Male
- Age 65

Situation Overview

In the immediate period after surgery, especially following major joint replacements, the goal is to provide a patient with sufficient pain control to allow ambulation and rehabilitative therapy. After major joint replacement, all patients will need some type of pain medication. However, some of the side effects of pain medications can be so debilitating that some patients would rather have higher levels of pain than have side effects such as nausea and vomiting.[2] Higher pain levels, though, may have their own deleterious physiological effects (eg, increased sympathetic activity) and can cause psychological stress. Additionally, providing a patient with sufficient pain control in a situation such as this may also have other health benefits. For example, while the use of anticoagulants helps prevent the occurrence of blood clots in the postoperative period, mobilizing the patient also is essential; however, it might be more difficult to achieve without sufficient pain control.[3]

Scenario

Mr. B is a 65-year-old patient who has just undergone a recent right knee replacement under spinal anesthesia. His past medical history is significant for hypertension and mild coronary artery disease with a single drug-eluting stent in one vessel placed more than 1 year ago. Cardiology has recommended he restart his antiplatelet therapy immediately after surgery. Mr. B is generally in good shape but is moderately obese. He plans to have rehabilitation therapy in the acute postoperative period. He is not able to tolerate intravenous patient-controlled analgesia due to side effects of itching, nausea, and mild agitation. By the patient's own assessment, he has borderline pain control. His heart rate and blood pressure are mildly elevated despite restarting his antihypertensive medication. The patient also complains that he has not had a bowel movement since his surgery and is uncomfortable.

Key Learning

An initial response to this patient might be to attempt to control all side

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effects with additional medications. While adding drugs to treat side effects often occurs gradually over time and may solve the problem to some degree, it is far from ideal, particularly in an older patient, to prescribe several medications for the sole reason of controlling side effects.

Application

There are several other pain management options to consider. One option is to alter the pain management method completely. The placement of a perineural catheter often allows the patient to have significant relief of pain in the acute postoperative period by using the infusion of a local anesthetic agent. This form of pain control could be adjusted during periods of rehabilitative therapy and could be continued after discharge from the hospital. The use of regional anesthetic techniques is appealing but often is limited by short duration. In almost all cases, supplementation with other agents, such as opioid analgesics, is required and beneficial. It is obviously not desirable to completely block nerve function because this would limit the patient's mobility and the ability to participate in physical therapy.

Should regional techniques not be available, simply converting to another opioid analgesic could offer some benefit. While there is some debate, many practitioners have observed that simply changing from one opioid analgesic to another, for instance using hydromorphone in place of morphine, can meaningfully improve a patient's response. Many patients often are more responsive to, or have fewer side effects from, one particular opioid analgesic compared with another. The technique of polypharmacy to control a series of medication side effects is not always ideal. The use of multimodal therapy to maximize pain control and minimize side effects is appealing. Multimodal therapy may allow a more effective treatment of pain by approaching it through different mechanisms.[4] While there is some debate on particular agents and their use in orthopedic surgery (eg, nonsteroidal anti-inflammatory drugs), the method of combining different classes of drugs appears to have good results. Patients may respond better to a combination of medications and experience reduced side effects.[4] In general, multimodal therapy may allow the optimization of therapeutic effect with minimization of side effects.[4]

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Treating Chronic Pain

by **Douglas L. Gourlay, MD, MSc, FRCPC, FASAM**
& **Howard A. Heit, MD, FACP, FASAM**

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Case Study Profile

- Treating chronic back pain
- Male
- Age 30

Situation Overview

Mr. Jones is a 30-year-old computer programmer who suffered a work-related fall 3 years ago, which resulted in a herniated lumbar disc. Multiple lumbar surgeries were performed, culminating in an L4-S1 fusion with pedicle screws and bone grafts from the iliac crest. Unfortunately, the patient continued to suffer from moderately severe central lumbar region pain (7 to 8 out of 10) with right-sided radicular symptoms. Recent nerve conduction studies and MRI suggest a failed back syndrome and the patient is not considered to be a candidate for surgery. He is referred to your office for management of his chronic back and leg pain.

Scenario

During the course of your risk assessment, you determine he has a CAGE Questionnaire Adapted to Include Drugs (CAGE–AID) score of 3 out of 4 and an Opioid Risk Tool (ORT) score of 10 which you interpret to suggest a significant risk for aberrant behavior. He has been in recovery from heroin abuse for the past 8 years and has been abstinent of all substances, including alcohol, for the past 2 years. Unfortunately, treatment with nonopioid analgesic pharmacotherapy and aggressive physical therapy has failed to meaningfully reduce his pain. His goal remains to improve sufficiently to return to work, at least on a part-time basis.

Key Learning

The key question here is not if there is risk, but rather, what is the risk, and more importantly, what is the best way to manage it? Mr. Jones, despite his elevated risk, has a potentially manageable pain syndrome which might respond to a cautious trial of opioid analgesic therapy. With carefully set limits and boundaries, including clearly identified treatment goals, his pain may be managed effectively.

It is important to clarify, from the outset, what Mr. Jones can expect from his treatment team and what his treatment team will need to expect of him. Specifically, patients suffering from chronic pain need to take an active role

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in their own pain management plan, including the management of possible risks for aberrant behavior.

By making Mr. Jones an integral part of the treatment team, we can explain the nature of a therapeutic trial of opioid analgesics and specifically define success of treatment. In addition, we can determine what strategies for exit management are available if opioid analgesics are shown to no longer be effective or a safe option for continued use.

Given the elevated risk in this case, a review with an addiction medicine specialist may result in a risk management plan that includes referral to, and co-management by, a pain specialist program. Once therapeutic goals are achieved, the patient can be transferred back to the primary care physician with the option of referral to a specialty service, if necessary.

Urine drug testing (UDT) plays an important role in managing risk in any treatment plan. Beyond its obvious role in risk management, UDT also allows for objective and credible advocacy for the patient with relevant third-parties such as insurers or concerned family members. The treating physician should avoid treatment with morphine and codeine, because it would result in the presence of morphine in the urine and make it difficult to identify the use of illegal opioid analgesics. Similarly, any use of dietary supplements and over-the-counter medications must be disclosed prior to the interpretation of UDT results.

Consistent with your clinic policy, this patient agrees to consent to communicate with all members of the treatment team.

As the patient progresses through treatment, he is able to gradually return to full-time employment with routine pain scores in the 2 to 3 out of 10 range, through the appropriate use of a combination of opioid and nonopioid analgesic pharmacotherapy. He continues to remain active in recovery programs. All objective and subjective measures continue to support the impression of clinical stability.

Application

When assessing a high-risk patient, it is important to establish your own level of comfort early on. By carefully assessing your experience and resources, it becomes easier to decide who to manage, co-manage, or refer on to specialty levels of care. As part of your assessment, keep in mind that predisposed does not mean predestined; an elevated risk profile complicates therapy, but it does not preclude it.

Risk management is a shared responsibility between the patient and the pain treatment team. Failure to establish an open relationship based on mutual trust and honesty can undermine even the most basic treatment goals.

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Using pixel tags, web beacons, clear GIFs, or other similar technologies: These may be used in connection with some Site pages and HTML-formatted e-mail messages to, among other things, track the actions of Site users and e-mail recipients, measure the success of our marketing campaigns, and compile statistics about Site usage and response rates.

Online behavioral advertising: The use of cookies, pixel tags, web beacons, clear GIFs, or other similar technologies allows our third-party vendors to deliver advertisements about our products and services when you visit the Site or other web sites or web properties across the Internet. These vendors may place pixel tags, web beacons, clear GIFs, or similar technologies on the Site and other websites or web properties, and also place or recognize third-party cookies when you visit the Site or other sites or web properties. They may use information about your visits to the Site and other web sites or web properties to provide advertisements about goods and services that may be of interest to you.

IP Address: Your IP Address is a number that is automatically assigned to the computer that you are using by your Internet Service Provider. An IP Address is identified and logged automatically in our server log files whenever a user visits the Site, along with the time of the visit and the page(s) that were visited. Collecting IP Addresses is standard practice on the Internet and is done automatically by many web sites. We use IP Addresses for purposes such as calculating Site usage levels, helping diagnose server problems, and administering the Site.

Device Information: We may collect information about your mobile device, such as a unique device identifier.

How We Use and Disclose Information

We use and disclose information you provide to us as described to you at the point of collection.

We also use information from or about you:

- to respond to your inquiries and fulfill your requests, such as to send you documents you request or e-mail alerts;
- to send you important information regarding our relationship with you or regarding the Site, changes to our terms, conditions, and policies and/or other administrative information; and
- for our business purposes, such as data analysis, audits, developing new products, enhancing our website, improving our products and services, identifying Site usage trends, personalizing your experience on the Site by presenting products and offers tailored to you, and determining the effectiveness of our promotional campaigns.

We also disclose information collected through the Site:

- to our affiliates for the purposes described in this Privacy Policy. A list of our affiliates is available here (click on the link for Form 10K, Exhibit 21, under “SEC Filings”). Janssen Pharmaceuticals, Inc is the party responsible for the management of the jointly-used Personal Information;
- to our third party partners with whom we offer a co-branded or co-marketed promotion;
- to our third party service providers who provide services such as website hosting and moderating, mobile application hosting, data analysis, payment processing, order fulfillment, infrastructure provision, IT services, customer service, e-mail and direct mail delivery services, credit card processing, auditing services, and other services, in order to enable them to provide services; and
- to a third party in the event of any reorganization, merger, sale, joint venture, assignment, transfer, or other disposition of all or any portion of our business, assets, or stock (including in connection with any bankruptcy or similar proceedings).

In addition, we use and disclose information collected through the Site as we believe to be necessary or appropriate: (a) as permitted by applicable law, including laws outside your country of residence; (b) to comply with legal process; (c) to respond to requests from public and government authorities, including public and government authorities outside your country of residence; (d) to enforce our terms and conditions; (e) to protect our operations or those of any of our affiliates; (f) to protect our rights, privacy, safety, or property, and/or that of our affiliates, you, or others; and (g) to allow us to pursue available remedies or limit the damages that we may sustain. We may also use and disclose information collected through the Site in other ways, with your consent.

We also use and disclose information we collect passively as described above, under “Passive Information Collection and Use,” and for any other purpose, except where we are required to do otherwise under applicable law (for example, if we are required to treat such information as personal information). In addition,

we may use and disclose information that is not in personally identifiable form for any purpose. If we combine information that is not in personally identifiable form with information that is (such as combining your name with your geographical location), we will treat the combined information as personal information as long as it is combined.

THIRD PARTY SITES AND SERVICES

This Privacy Policy does not address, and we are not responsible for, the privacy, information, or other practices of any third parties, including any third party operating any site or web property (including, without limitation, any application) that is available through this Site or to which this Site contains a link. The availability of, or inclusion of a link to, any such site or property on the Site does not imply endorsement of it by us or by our affiliates.

SECURITY

We use reasonable organizational, technical, and administrative measures to protect personal information under our control. Unfortunately, no data transmission over the Internet or data storage system can be guaranteed to be 100% secure. If you have reason to believe that your interaction with us is no longer secure (for example, if you feel that the security of any account you have with us has been compromised), please immediately notify us of the problem by contacting us in accordance with the "*Contacting Us*" section below.

CHOICES AND ACCESS

Your choices regarding our use and disclosure of your personal information

We give you choices regarding our use and disclosure of your personal information for marketing purposes. You may opt out from:

- **Receiving marketing communications from us:** If you no longer want to receive marketing communications from us on a going-forward basis, you may opt out of receiving them by contacting us at 1-800-JANSSEN (526-7736) or send a written request to Janssen Medical Information, PO Box 200 Titusville, NJ 08560. In your response to us, please provide your name, identify the form(s) of marketing communications that you no longer wish to receive, and include the address(es) to which it/they are sent. For example, if you no longer wish to receive marketing e-mails or direct mail from us, tell us that, and provide your name and e-mail or postal address.
- **Receiving reminders from us:** If you no longer want to receive medical reminders from us on a going-forward basis, you may opt out of receiving them by contacting us at 1-800-JANSSEN (526-7736) or send a written request to Janssen Medical Information, PO Box 200 Titusville, NJ 08560. In your response to us, please provide your name and the e-mail address or phone number at which you receive reminders from us.
- **Our sharing of your personal information with affiliates and third-party partners:** If you would prefer that we not share your personal information on a going-forward basis with our affiliates and/or third-party partners for their marketing purposes, you may opt out of this sharing by contacting at 1-800-JANSSEN (526-7736) or send a written request to Janssen Medical Information, PO Box 200 Titusville, NJ 08560. In your response to us, please state that we should no longer share your personal information with our affiliates and/or third-party partners for their marketing purposes, and include your name and e-mail address.

We will seek to comply with your request(s) as soon as reasonably practicable. Please note that if you opt out as described above, we will not be able to remove your personal information from the databases of our affiliates with which we have already shared your information (*i.e.*, as of the date that we implement your opt-out request). Please also note that if you opt out of receiving marketing-related messages from us, we may still send you important transactional and administrative messages, from which you cannot opt out.

How you can access, change, or delete your personal information

If you would like to review, correct, update, or delete the personal information that you have provided via the Site, please contact us at 1-800-JANSSEN (526-7736) or send a written request to Janssen Medical Information, PO Box 200 Titusville, NJ 08560. We will try to comply with your request as soon as reasonably practicable.

RETENTION PERIOD

We retain your personal information for the period necessary to fulfill the purposes outlined in this Privacy Policy, unless a longer retention period is required or allowed by law or to otherwise fulfill a legal obligation.

USE OF SITE BY MINORS

The Site is not directed to individuals under the age of 18, and we request that these individuals not provide Personal Information through the Site.

CROSS-BORDER TRANSFER

Your personal information may be stored and processed in any country where we have facilities or service providers, and by using our Site or by providing consent to us (where required by law), you agree to the transfer of information to countries outside of your country of residence, including to the United States, which may provide for different data protection rules than in your country.

SENSITIVE INFORMATION

Unless we specifically request or invite it, we ask that you not send us, and you not disclose, any sensitive personal information (*e.g.*, information related to racial or ethnic origin, political opinions, religion or other beliefs, health, criminal background or trade union membership) on or through the Site or otherwise to us. In those cases where we may request or invite you to provide sensitive information, we will do so with your express consent.

UPDATES TO THIS PRIVACY POLICY

We may change this Privacy Policy. Any changes to this Privacy Policy will become effective when we post the revised Privacy Policy on the Site. Your use of the Site following these changes means that you accept the revised Privacy Policy. This Privacy Policy was last updated September 2013.

CONTACTING US

If you have any questions about this Privacy Policy, please contact us at 1-800-JANSSEN (526-7736) or send a written request to Janssen Medical Information, PO Box 200 Titusville, NJ 08560.

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